UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM	10-Q
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(Mark	(One)				
×		ORT PURSUANT TO	SECTION 13 OR 15(d) OF THE S	ECURITIES EXCHANGE ACT OF 1934	
		For	the quarterly period ended Sept OR	ember 30, 2022	
	TRANSITION REPO	ORT PURSUANT TO	SECTION 13 OR 15(d) OF THE S	ECURITIES EXCHANGE ACT OF 1934	
		For the tr	ansition period from	to	
			Commission File Number: 00	01-40489	
				_	
		VERV	E THERAPEU	TICS, INC.	
		(Exac	t Name of Registrant as Specific	ed in its Charter)	
				<u> </u>	
	(\$	Delaware State or other jurisdiction of		82-4800132 (I.R.S. Employer	
		corporation or organization)		Identification No.)	
	Во	ookline Avenue, Suite ston, Massachusetts ss of principal executive offic	;	02215 (Zip Code)	
		Registrant's	telephone number, including ar	ea code: (617) 603-0070	
			F00 Toohnology Square Su	ita 904	
			500 Technology Square, Su Cambridge, Massachusetts		
		(Forme	er Name, Former Address and Former if Changed Since Last Re		
	Securities registered	d pursuant to Section 12(-	port)	
		each class	Trading Symbol(s)	Name of each exchange on which registered	
	Common stock, par	value \$0.001 per share	VERV	Nasdaq Global Select Market	
	during the preceding 1	ark whether the registrar 2 months (or for such sho days. Yes ⊠ No □	orter period that the registrant was rec	e filed by Section 13 or 15(d) of the Securities Exchange Aquired to file such reports), and (2) has been subject to such	ct of h filing
				nteractive Data File required to be submitted pursuant to Ru horter period that the registrant was required to submit such	
		any. See the definitions		erated filer, a non-accelerated filer, a smaller reporting comed filer," "smaller reporting company," and "emerging growth	
La	rge accelerated filer			Accelerated filer	
No	n-accelerated filer	\boxtimes		Smaller reporting company	
				Emerging growth company	\boxtimes
new (0 00		check mark if the registrant has electe ed pursuant to Section 13(a) of the Ex	d not to use the extended transition period for complying w change Act. $\hfill\Box$	ith any
	Indicate by check m	ark whether the registrar	nt is a shell company (as defined in Ru	lle 12b-2 of the Exchange Act). Yes \square No \boxtimes	
	As of November 3, 2	2022, the registrant had 6	61,603,788 shares of common stock, p	par value \$0.001 per share, outstanding.	

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "project," "should," "target," "will," "would," or the negative of these words or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- the initiation, timing, progress and results of our research and development programs, preclinical studies and clinical trials, including the timing of our submissions of investigational new drug, or IND, applications, and clinical trial applications to regulatory authorities;
- the timing and conduct of our heart-1 clinical trial, an ongoing Phase 1 clinical trial of VERVE-101, including statements regarding the timing of enrollment and completion of the clinical trials and the period during which the results of the clinical trials will become available;
- our expectations related to the hold that the U.S. Food and Drug Administration, or FDA, placed on our IND application to conduct a clinical trial evaluating VERVE-101 in the United States, including the communication plans and timing of the FDA and our plans and expectations for discussions with the FDA and the outcomes from the discussions;
- our estimates regarding expenses, future revenue, capital requirements, need for additional financing and the period over which we believe our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements;
- the timing of and our ability to submit applications for and obtain and maintain regulatory approvals for our current and future product candidates;
- the potential therapeutic attributes and advantages of our current and future product candidates;
- our expectations about the translatability of non-human primates results into humans;
- our plans to develop and, if approved, subsequently commercialize any product candidates we may develop;
- · the rate and degree of market acceptance and clinical utility of our products, if approved;
- our estimates regarding the addressable patient population and potential market opportunity for our current and future product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expectations regarding our ability to obtain and maintain intellectual property protection;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- · the impact of government laws and regulations;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available;
- · developments relating to our competitors and our industry;
- our ability to establish and maintain collaborations or obtain additional funding;
- the impact of the ongoing COVID-19 pandemic and our response to the pandemic; and
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that

we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments we may make or enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits to our other filings with the Securities and Exchange Commission completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Except where the context otherwise requires or where otherwise indicated, the terms "we," "us," "our," "our company," "the company," and "our business" in this Quarterly Report on Form 10-Q refer to Verve Therapeutics, Inc. and its consolidated subsidiary.

RISK FACTOR SUMMARY

Our business is subject to a number of risks of which you should be aware before making an investment decision. Below we summarize what we believe to be the principal risks facing our business, in addition to the risks described more fully in Item 1A, "Risk Factors" of Part II of this Quarterly Report on Form 10-Q and other information included in this report. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations.

If any of the following risks occurs, our business, financial condition and results of operations and future growth prospects could be materially and adversely affected, and the actual outcomes of matters as to which forward-looking statements are made in this report could be materially different from those anticipated in such forward-looking statements:

- We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts;
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability;
- We are very early in our development efforts, and we only recently initiated our first clinical trial of a product candidate, VERVE-101, our
 product candidate targeting PCSK9. As a result, we expect it will be many years before we commercialize any product candidate, if ever.
 If we are unable to advance our current or future product candidates into and through clinical trials, obtain marketing approval and
 ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed:
- The U.S. Food and Drug Administration, or the FDA, has placed the investigational new drug application to conduct a clinical trial evaluating VERVE-101 in the United States on hold. We cannot be certain that the hold will be lifted on a timely basis, or at all, and we may not be able to initiate our clinical trial of VERVE-101 in the United States;
- Gene editing, including base editing, is a novel technology in a rapidly evolving field that is not yet clinically validated as being safe and efficacious for human therapeutic use. The approaches we are taking to discover and develop novel therapeutics are unproven and may never lead to marketable products. We are focusing our research and development efforts for VERVE-101 and VERVE-201, our product candidate targeting ANGPTL3, on gene editing using base editing technology, but other gene editing technologies may be discovered that provide significant advantages over base editing and we may not be able to access or use those technologies, which could materially harm our business. We are also seeking to discover new gene editing technologies and may not be successful in doing so;
- The outcome of preclinical studies and earlier-stage clinical trials may not be predictive of future results or the success of later preclinical studies and clinical trials;
- If any of the product candidates we may develop, or the delivery modes we rely on to administer them, cause serious adverse events, undesirable side effects or unexpected characteristics, such events, side effects or characteristics could delay or prevent regulatory approval of the product candidates, limit the commercial potential or result in significant negative consequences following any potential marketing approval:
- Adverse public perception of genetic medicines, and gene editing and base editing in particular, may negatively impact regulatory
 approval of, and/or demand for, our potential products;
- Genetic medicines are complex and difficult to manufacture. We could experience delays in satisfying regulatory authorities or production problems that result in delays in our development programs, limit the supply of our product candidates we may develop, or otherwise harm our business:
- We rely, and expect to continue to rely, on third parties to conduct some or all aspects of our product manufacturing, research and preclinical and clinical testing, and these third parties may not perform satisfactorily;
- We have entered into collaborations, and may enter into additional collaborations, with third parties for the research, development, manufacture and commercialization of programs or product candidates. If these collaborations are not successful, our business could be adversely affected;
- If we or our licensors are unable to obtain, maintain, defend and enforce patent rights that cover our gene editing technology and product
 candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize
 technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product
 candidates may be adversely affected;

- If we fail to comply with our obligations in our intellectual property license arrangements with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business;
- The intellectual property landscape around genome editing technology, including base editing, is highly dynamic, and third parties may
 initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the
 outcome of which would be uncertain and may prevent, delay or otherwise interfere with our product discovery, development and
 commercialization efforts;
- We face substantial competition, which may result in others discovering, developing or commercializing products before us or more successfully than we do; and
- The ongoing COVID-19 pandemic may affect our ability to initiate and complete preclinical studies, delay the initiation of future clinical
 trials, disrupt regulatory activities or have other adverse effects on our business and operations. In addition, this pandemic has adversely
 impacted economies worldwide, which could result in adverse effects on our business, operations and ability to raise capital.

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Part I — Financial Information

Item 1. Financial Statements

Verve Therapeutics, Inc. Condensed consolidated balance sheets

(in thousands, except share and per share amounts) (unaudited)	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 277,019	\$ 64,330
Marketable securities	273,691	296,112
Collaboration receivable	929	_
Prepaid expenses and other current assets	9,991	6,686
Total current assets	561,630	367,128
Property and equipment, net	15,159	7,224
Restricted cash	4,824	5,237
Operating lease right-of-use assets	91,332	1,839
Other long-term assets	410	2,696
Total assets	\$ 673,355	\$ 384,124
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 465	\$ 7,077
Accrued expenses	19,649	12,992
Lease liability, current portion	8,904	1,955
Total current liabilities	 29,018	22,024
Long-term lease liability	71,011	_
Success payment liability	5,062	4,371
Deferred revenue, non-current	20,014	_
Other long-term liabilities	307	377
Total liabilities	125,412	26,772
Commitments and contingencies (See Note 7 and Note 8)	·	·
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding at September 30, 2022 and December 31, 2021	_	_
Common stock, \$0.001 par value; 200,000,000 shares authorized, 60,443,175 and 48,511,735 shares issued and outstanding at September 30, 2022 and December 31,		
2021, respectively	61	49
Additional paid-in capital	851,954	544,381
Accumulated other comprehensive loss	(920)	(228)
Accumulated deficit	 (303,152)	(186,850)
Total stockholders' equity	 547,943	357,352
Total liabilities and stockholders' equity	\$ 673,355	\$ 384,124

The accompanying notes are an integral part of these condensed consolidated financial statements.

Verve Therapeutics, Inc. Condensed consolidated statements of operations and comprehensive loss

	Three months ended September 30,				Ni	ne months end	ed S	eptember 30,
(in thousands, except share and per share amounts) (unaudited)		2022		2021		2022		2021
Collaboration revenue	\$	929	\$	_	\$	929	\$	_
Operating expenses:								
Research and development		35,197		17,495		92,811		42,263
General and administrative		9,592		6,007		26,095		12,264
Total operating expenses		44,789		23,502		118,906		54,527
Loss from operations	'	(43,860)		(23,502)		(117,977)		(54,527)
Other (expense) income:								
Change in fair value of antidilution rights liability		_		_		_		(25,574)
Change in fair value of success payment liability		(3,306)		700		(691)		(8,954)
Interest and other income, net		1,976		53		2,366		78
Total other (expense) income, net		(1,330)		753		1,675		(34,450)
Net loss	\$	(45,190)	\$	(22,749)	\$	(116,302)	\$	(88,977)
Net loss per common share attributable to common stockholders, basic and diluted	\$	(0.79)	\$	(0.47)	\$	(2.26)	\$	(4.52)
Weighted-average common shares used in net loss per share attributable to common stockholders, basic and diluted		57,207,125		47,992,773		51,516,037		19,698,450
Comprehensive Loss:								
Net loss	\$	(45,190)	\$	(22,749)	\$	(116,302)	\$	(88,977)
Other comprehensive income (loss):		Í						
Unrealized income (loss) on marketable securities		18		(5)		(692)		(10)
Comprehensive loss	\$	(45,172)	\$	(22,754)	\$	(116,994)	\$	(88,987)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Verve Therapeutics, Inc.

Condensed consolidated statements of convertible preferred stock and stockholders' equity (deficit)

	Converti	ble pi	referred stock		Com	mon stock								
(in thousands, except share amounts) (unaudited)	Shares		Amount	Shares		Amount	,	Additional paid-in capital	coı	ocumulated other mprehensiv e come (loss)	A	ccumulate d deficit	sto	Total ockholder s' equity (deficit)
Balance at December 31, 2020	179,519,			2,585,78				•		<u> </u>				
	032	\$	125,160	9	\$	3	\$	2,616	\$	8	\$	(66,536)	\$	(63,909)
Issuance of Series B convertible preferred stock, net of issuance costs of \$241	77,163,0 22		93,759	_		_		_		_		_		_
Vesting of restricted common stock	_		_	134,409		_		_		_		_		_
Exercise of stock options	_		_	48,745		_		72		_		_		72
Unrealized loss on available-for-sale securities	_		_	_		_		_		(1)		_		(1)
Stock-based compensation	_		_	_		_		670		_		_		670
Net loss	_		_	_		_		_		_		(13,263)		(13,263)
Balance at March 31, 2021	256,682, 054	\$	218,919	2,768,94 3	\$	3	\$	3,358	\$	7	\$	(79,799)	\$	(76,431)
Conversion of convertible preferred stock to common stock upon closing of initial public offering	(256,682, 054)		(218,919)	27,720,9 23		28		218,891		_		_		218,919
Issuance of common stock from initial public offering, net of issuance costs of \$25,098	_		_	16,141,1 57		16		281,568		_		_		281,584
Issuance of common stock to licensor institutions	_		_	878,098		1		32,489		_		_		32,490
Vesting of restricted common stock	_		_	134,408		_				_		_		_
Exercise of stock options	_		_	303,467		_		452		_		_		452
Unrealized loss on available-for-sale securities	_		_	_		_		_		(4)		_		(4)
Stock-based compensation	_		_	_		_		1,351				_		1,351
Net loss	_		_	_		_				_		(52,965)		(52,965)
Balance at June 30, 2021		\$	_	47,946,9 96	\$	48	\$	538,109	\$	3	\$	(132,764)	\$	405,396
Vesting of restricted common stock		<u> </u>		134,408	<u> </u>	_	<u> </u>	_		_				
Unrealized loss on available-for-sale securities	_		_			_		_		(5)		_		(5)
Stock-based compensation	_		_			_		2,293		-		_		2,293
Net loss	_		_	_		_		_,		_		(22,749)		(22,749)
Balance at September 30, 2021		\$	_	48,081,4 04	\$	48	\$	540,402	\$	(2)	\$, , ,	\$	384,935
				-	·			, -	•		Ė	(==,= = ,		
Balance at December 31, 2021	_	\$	_	48,511,7 35	\$	49	\$	544,381	\$	(228)	\$	(186,850)	\$	357,352
Exercise of stock options	_		_	143,506		_		505		_		_		505
Unrealized loss on available-for-sale securities	_		_	_		_		_		(504)		_		(504)
Stock-based compensation	_		_	_		_		4,203		_		_		4,203
Net loss	_		_	_		_		_		_		(30,166)		(30,166)
Balance at March 31, 2022				48,655,2										
		\$		41	\$	49	\$	549,089	\$	(732)	\$	(217,016)	\$	331,390
Exercise of stock options	_		_	29,193		_		120		_		_		120
Issuance of common stock under employee stock purchase plan	_		_	25,218		_		325		_		_		325
Unrealized loss on available-for-sale securities	_		_	_		_		_		(206)		_		(206)
Stock-based compensation	_		_	_		_		5,650		_		_		5,650
Net loss				_						_		(40,946)		(40,946)
Balance at June 30, 2022	_	\$	_	48,709,6 52	\$	49	\$	555,184	\$	(938)	\$	(257,962)	\$	296,333
Exercise of stock options			_	413,503		_		1,107						1,107
Issuance of common stock in connection with the Vertex Agreement	_		_	1,519,75 6		2		39,985		_		_		39,987
Issuance of common stock from follow-on public offering, net of issuance costs of \$15.9 million	_		_	9,583,33 4		10		242,838		_		_		242,848

Issuance of common stock from At-the- Market offering, net of issuance costs of \$0.6 million	_		216,930	_	6,920	_	_	6,920
Unrealized gain on available-for-sale securities	_	_	_	_	_	18	_	18
Stock-based compensation	_	_	_	_	5,920	_	_	5,920
Net loss	_	_	_	_	_	_	\$ (45,190)	(45,190)
Balance at September 30, 2022		. –	60,443,1 75	\$ 61	\$ 851.954	\$ (920)) \$ (303.152)	\$ 547.943

The accompanying notes are an integral part of these condensed consolidated financial statements.

Verve Therapeutics, Inc. Condensed consolidated statements of cash flows

		Nine months e	nded	September 30,
(unaudited, in thousands)	-	2022		2021
Cash flows from operating activities:				
Net loss	\$	(116,302)	\$	(88,977)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation		1,879		1,063
Non-cash lease expense		2,279		1,345
Amortization of premium on marketable securities		1,114		768
Stock-based compensation		15,773		4,314
Change in fair value of antidilution rights		_		25,574
Change in fair value of success payments liabilities		691		8,954
Changes in operating assets and liabilities:				
Collaboration receivable		(929)		_
Prepaid expenses and other assets		(9,368)		(5,667)
Accounts payable		(6,411)		3,344
Accrued expenses and other liabilities		4,661		864
Operating lease liabilities		(2,841)		(1,419)
Deferred revenue		20,014		_
Net cash used in operating activities		(89,440)		(49,837)
Cash flows from investing activities:				
Purchases of property and equipment		(8,264)		(3,378)
Purchases of marketable securities		(222,078)		(234,490)
Maturities of marketable securities		242,700		55,755
Net cash provided by investing activities		12,358		(182,113)
Cash flows from financing activities:				
Proceeds from issuance of Preferred Stock, net		_		93,759
Proceeds from initial public offering, net of underwriting discount		_		285,214
Proceeds from the issuance of common stock in connection with the Vertex Agreement		39,986		_
Proceeds from issuance of common shares, net of commissions		247,919		_
Payment of equity offering costs		(605)		(3,632)
Proceeds from exercise of stock options		1,733		524
Issuance of shares through employee stock purchase plan		325		_
Net cash provided by financing activities		289,358		375,865
Increase in cash, cash equivalents and restricted cash		212,276		143,915
Cash, cash equivalents and restricted cash—beginning of period		69,567		9,456
Cash, cash equivalents and restricted cash—end of period	\$	281,843	\$	153,371
Supplemental disclosure of noncash investing and financing activities:				,
Property and equipment additions included in accounts payable and accrued expenses	\$	2,025	\$	361
Offering costs included in accounts payable and accrued liabilities	\$	175	\$	_
Conversion of convertible preferred stock to common stock upon closing of initial public	T		7	
offering	\$	_	\$	218,919
Settlement of antidilution rights liability by issuing common stock	\$	_	\$	32,490
Right-of-use assets obtained in exchange for new operating lease liabilities	\$	81,244	\$	809

The accompanying notes are an integral part of these condensed consolidated financial statements.

Verve Therapeutics, Inc. Notes to condensed consolidated financial statements (unaudited)

1. Nature of the business and basis of presentation

Organization

Verve Therapeutics, Inc. (the "Company" or "Verve") is a genetic medicines company pioneering a new approach to the care of cardiovascular disease, transforming treatment from chronic management to single-course gene editing medicines. The Company was incorporated on March 9, 2018 as Endcadia, Inc., a Delaware corporation, and began operations shortly thereafter. In January 2019, the Company amended its certificate of incorporation to change its name to Verve Therapeutics, Inc. The Company's principal offices are located in Boston, Massachusetts.

Liquidity and capital resources

Since its inception, the Company has devoted its efforts principally to research and development and raising capital. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, technical risks associated with the successful research, development and manufacturing of product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Current and future programs will require significant research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

In connection with the Company's initial public offering, or IPO, in June 2021, the Company effected a one-for-9.2595 reverse stock split of the Company's issued and outstanding common stock. Accordingly, all shares of common stock and per share amounts, as well as the conversion ratio of the Company's outstanding convertible preferred stock, for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split, including reclassification of par and additional paid-in capital amounts as a result of the reverse stock split.

On July 18, 2022, the Company entered into a Strategic Collaboration and License Agreement (the "Vertex Agreement") with Vertex Pharmaceuticals Incorporated ("Vertex") for an exclusive, four-year worldwide research collaboration focused on developing *in vivo* gene editing candidates toward an undisclosed target for the treatment of a single liver disease, as further described in Note 8, "License agreements." Pursuant to the Vertex Agreement, Vertex paid the Company \$25.0 million in an upfront payment on July 20, 2022. The Company is eligible to receive (i) success payments of up to \$22 million for each product candidate (up to a maximum of \$66 million) that achieves the applicable development criteria and (ii) up to an aggregate of \$340 million in development and commercial milestone payments. The Company is also eligible to receive tiered single-digit royalties on net sales, subject to specified reductions.

On July 18, 2022, in connection with the execution of the Vertex Agreement, the Company also entered into a stock purchase agreement with Vertex (the "Stock Purchase Agreement") for the sale and issuance of 1,519,756 shares of the Company's common stock to Vertex at a price of \$23.03 per share, which was equal to the five-day volume-weighted average share price as of July 15, 2022, for an aggregate purchase price of \$35.0 million (the "Private Placement"). The Private Placement closed on July 20, 2022.

On July 25, 2022, the Company completed a follow-on public offering of common stock, pursuant to which the Company issued and sold 9,583,334 shares of its common stock, including an additional 1,250,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, at a public offering price of \$27.00 per share, for aggregate net proceeds of approximately \$242.9 million after deducting underwriting discounts and commissions of approximately \$15.5 million and offering costs of approximately \$0.3 million.

On July 1, 2022, the Company entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") as the agent pursuant to which the Company is entitled to offer and sell, from time to time at prevailing market prices, shares of the Company's common stock. The Company agreed to pay Jefferies a commission of up to 3.0% of the aggregate gross sale proceeds of any shares sold by Jefferies under the Sales Agreement. Any sales under the Sales Agreement will be made pursuant to the Company's registration statement on Form S-3 (File No 333-267578), which

became effective on September 23, 2022, with an aggregate offering price of up to \$200.0 million. As of September 30, 2022, the Company had sold 216,930 shares of its common stock under the Sales Agreement for aggregate net proceeds of \$7.3 million, after deducting commissions and offering expenses payable by the Company. The Company sold an additional 1,063,238 shares of its common stock under the Sales Agreement for aggregate net proceeds of \$36.0 million subsequent to September 30, 2022.

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company expects that its cash, cash equivalents and marketable securities of \$550.7 million as of September 30, 2022, will be sufficient to fund its operations and capital expenditure requirements beyond the next 12 months from the date of issuance of these financial statements. The Company will need additional financing to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. The inability to raise capital as and when needed could have a negative impact on the Company's financial condition and its ability to pursue its business strategy. The Company will need to generate significant revenue to achieve profitability, and it may never do so.

Basis of presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of the Company's management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments that are necessary to present fairly the Company's financial position as of September 30, 2022, the results of its operations and other comprehensive loss for the three and nine months ended September 30, 2022 and 2021, convertible preferred stock and stockholders' equity for the three and nine months ended September 30, 2022 and 2021 and cash flows for the nine months ended September 30, 2022 and 2021. Such adjustments are of a normal and recurring nature. The results for the three and nine months ended September 30, 2022 are not necessarily indicative of the results for the year ending December 31, 2022, or for any future period. These interim financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2021, and the notes thereto, included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2022.

2. Summary of significant accounting policies

The Company's significant accounting policies are disclosed in Note 2, "Summary of significant accounting policies," in the audited consolidated financial statements for the year ended December 31, 2021, and notes thereto, included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2022. Since the date of those financial statements, the Company has additionally adopted the revenue recognition policy discussed further below. There have been no other changes to the Company's significant accounting policies.

Cash, cash equivalents and restricted cash

Restricted cash represents collateral provided for letters of credit issued as security deposits in connection with the Company's leases of its corporate facilities. A reconciliation of the cash, cash equivalents, and restricted cash reported within the balance sheet that sum to the total of the same amounts shown in the statement of cash flows is as follows:

	September 30,	September 30,
(in thousands)	2022	2021
Cash and cash equivalents	\$ 277,019	\$ 148,134
Restricted cash	4,824	5,237
Total cash, cash equivalents and restricted cash	\$ 281,843	\$ 153,371

Recently adopted accounting pronouncements

Leases

During the quarter ended September 30, 2021, the Company early adopted ASC Topic 842, "Leases" ("ASC 842") using the revised modified retrospective approach as of January 1, 2021. The unaudited interim condensed consolidated financial statements for the three and nine months ended September 30, 2021 have been retroactively adjusted to reflect the adoption of ASC 842, including retroactive adjustments to the unaudited interim condensed consolidated statement of cash flows and certain additional footnote disclosures as included herein. The adoption of ASC 842 had no material impact to the Company's unaudited condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2021.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on specific facts and circumstances, the existence of an identified asset(s), if any, and the Company's control over the use of the identified asset(s), if applicable. The lease liability is measured at the present value of future lease payments, discounted using the discount rate as of the lease commencement date. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the incremental borrowing rate, which is the rate incurred to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. The Company recognizes a corresponding lease right of use ("ROU") asset, initially measured as the amount of lease liability, adjusted for any initial lease costs or lease payments made before or at the commencement of the lease, and reduced by any lease incentives.

The Company's leases consist of only operating leases. Operating leases are recognized on the balance sheet as ROU lease assets, lease liabilities current and lease liabilities non-current. Fixed rents are included in the calculation of the lease balances while certain variable costs paid for certain operating and pass-through costs are excluded. Lease expense is recognized over the expected term on a straight-line basis.

Revenue Recognition

The Company enters into collaboration agreements which are within the scope of ASC Topic 606, "Revenue from Contracts with Customers" ("ASC 606"), under which the Company licenses rights to certain of the Company's product candidates and performs research and development services. The terms of these arrangements typically include payment of one or more of the following: non-refundable, upfront fees; reimbursement of research and development costs; development, regulatory, and commercial milestone payments; and royalties on net sales of licensed products.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The promised goods or services in the Company's arrangements typically consist of license rights to the Company's intellectual property and research and development services. The Company provides options to additional items in the contracts, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available and whether the goods or services are integral or dependent to other goods or services in the contract.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the number of potential payments and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected amount method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration which is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The Company's contracts often include development and regulatory milestone payments which are assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues in the period of adjustment. To date, the Company has not recognized any consideration related to the achievement of development, regulatory, or commercial milestone revenue resulting from any of the Company's collaboration arrangements.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any consideration related to sales-based royalty revenue resulting from any of the Company's collaboration arrangements.

The Company allocates the transaction price based on the estimated stand-alone selling price of each of the performance obligations. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price for service obligations, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Additionally, in determining the standalone selling price for material rights, the Company utilizes comparable transactions, clinical trial success probabilities, and estimates of option exercise likelihood. Variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts the Company would expect to receive for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Upfront payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

3. Marketable securities

Marketable securities by security type consisted of the following:

			Gross unrealized losses*	ptemb	er 30, 2022
(in thousands)	Amortized cost	Gross unrealized gains	unrealize	ed	Fair value
U.S. treasury bills and notes	\$ 142,678	\$ _	\$ (6:	39) \$	142,039
U.S. agency securities	131,933	3	(28	34)	131,652
Total	\$ 274 611	\$ 3	\$ (9)	23) \$	273 691

					Decem	ber 3	1, 2021
(in thousands)	Amortized cos		Gross unrealized gains		Gross unrealized losses*		Fair value
U.S. treasury bills and notes	\$ 277.559			\$	(218)	\$ 2	277,341
U.S. agency securities	18,78		_	•	(10)	•	18,771
Total	\$ 296,340) \$	_	\$	(228)	\$ 2	296,112

^{*}The Company reviews its marketable securities for impairment each period whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable. As of September 30, 2022 and December 31, 2021, the Company expected its investments to recover through the remaining term of the security and concluded no impairment existed.

The remaining contractual maturities of all marketable securities were less than one year as of September 30, 2022 and December 31, 2021.

4. Property and equipment, net

Property and equipment, net, consist of the following:

(in thousands)	September 30, 2022	December 31, 2021
Lab equipment	\$ 15,887	\$ 8,567
Furniture and fixtures	2,452	566
Computer equipment	739	158
Leasehold improvements	293	266
Total property and equipment	19,371	9,557
Less accumulated depreciation	(4,212)	(2,333)
Property and equipment, net	\$ 15,159	\$ 7,224

The following table summarizes depreciation expense incurred:

	Three months ended September 30,				Nine months	ended	September 30,
(in thousands)	 2022		2021		2022		2021
Depreciation expense	\$ 717	\$	412	\$	1,879	\$	1,063

5. Fair value of financial instruments

The Company's financial instruments that are measured at fair value on a recurring basis consist of money market funds, marketable securities, and a derivative liability (success payment liability) pursuant to our license agreements with the President and Fellows of Harvard College ("Harvard"), and The Broad Institute, Inc.("Broad"), which license agreements are referred to herein as the Harvard/Broad License Agreement and Broad License Agreement.

The following tables set forth the fair value of the Company's financial instruments by level within the fair value hierarchy:

			As of Sept	embe	r 30, 2022
(in thousands)	Fair value	Level 1	Level 2		Level 3
<u>Assets</u>					
Money market funds	\$ 184,677	\$ 184,677	\$ _	\$	_
Marketable securities:					
U.S. treasury bills and notes	142,039	_	142,039		_
U.S. agency securities	131,652	_	131,652		_
Total assets	\$ 458,368	\$ 184,677	\$ 273,691	\$	_
<u>Liabilities</u>					
Success payment liability	\$ 5,062	\$ _	\$ _	\$	5,062
Total liabilities	\$ 5,062	\$ _	\$ _	\$	5,062

As of December 31, 2021

(in thousands)	 Fair value	Level 1	Level 2	Level 3
<u>Assets</u>				
Money market funds	\$ 58,127	\$ 58,127	\$ _	\$ _
Marketable securities:				
U.S. treasury bills and notes	277,341	_	277,341	_
U.S. agency securities	18,771	_	18,771	_
Total assets	\$ 354,239	\$ 58,127	\$ 296,112	\$
<u>Liabilities</u>				
Success payment liability	\$ 4,371	\$ _	\$ _	\$ 4,371
Total liabilities	\$ 4,371	\$ _	\$ _	\$ 4,371

Cash Equivalents—Cash equivalents of \$184.7 million and \$58.1 million as of September 30, 2022 and December 31, 2021, respectively, consisted of money market funds and are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets.

Marketable Securities—The Company measures its marketable securities at fair value on a recurring basis and classifies those instruments within Level 2 of the fair value hierarchy. Marketable securities are classified within Level 2 of the fair value hierarchy because pricing inputs are other than quoted prices in active markets, which are either directly or indirectly observable as of the reporting date, and fair value is determined through the use of models or other valuation methodologies.

Antidilution Rights Liability—The antidilution rights liability represented the obligation to issue additional shares of common stock to Harvard and Broad following the completion of (1) a defined aggregate level of preferred stock financing and (2) either a sale of the Company's preferred stock, an initial public offering, or a company sale meeting a certain value threshold. The antidilution rights liability is stated at fair value and is considered Level 3 in the fair value hierarchy because its fair value measurement is based, in part, on significant inputs not observed in the market. The antidilution rights liability related to meeting a defined aggregate level of preferred stock financing was valued using a probability-weighted present value model that considered the probability of meeting the defined aggregate level of preferred stock financing, as well as the fair value of the Company's common stock. The antidilution rights liability related to the achievement of a specified valuation through either a sale of the Company's preferred stock, an initial public offering, or a company sale was valued using a Monte Carlo simulation model, which models the value of the liability based on several key variables, including probability of event occurrence, timing of event occurrence, as well as the fair value of the Company's common stock.

In June 2021, upon completion of its IPO, the Company settled the antidilution rights liability in full through the issuance of 878,098 shares of the Company's common stock for a settlement amount of \$32.5 million. Prior to settlement, the Company remeasured the liability with a corresponding increase of \$25.6 million to other expense for the year ended December 31, 2021.

Success Payment Liability—The Company is obligated to pay to Harvard and Broad tiered success payments in the event its average market capitalization exceeds specified thresholds for a specified period of time ascending from a high nine-digit dollar amount to \$10.0 billion, or sale of the Company for consideration in excess of those thresholds. In the event of a change of control or a sale of the Company, the Company is required to pay success payments in cash within a specified period following such event. Otherwise, the success payments may be settled at the Company's option in either cash or shares of its common stock, or a combination of cash and shares of its common stock. The maximum aggregate success payments that could be payable by the Company is \$31.3 million (after termination of the Broad License Agreement).

The success payments liability is stated at fair value and is considered Level 3 because its fair value measurement is based, in part, on significant inputs not observed in the market. The Company used a Monte Carlo simulation model, which models the value of the liability based on several key variables, including probability of event occurrence, timing of event occurrence, as well as the value of the Company's common stock. The Company also estimated the likelihood that it would maintain the Harvard/Broad License Agreement based on its ongoing research efforts.

The Company remeasured the liability at fair value with increases of \$3.3 million and \$0.7 million recorded to other income for the three and nine months ended September 30, 2022, respectively. The Company remeasured the liability at fair value with a decrease of \$0.7 million recorded to other income for the three months ended September 30, 2021 and an increase of \$9.0 million recorded to other expense for the nine months ended September 30, 2021.

In September 2021, multiple success payments were triggered and amounts due to Harvard and Broad totaled \$6.3 million. These amounts were settled in cash in November 2021. The Company will continue to adjust the remaining success payment liability for changes in fair value until the earlier of the achievement or expiration of the obligation.

The primary inputs used in valuing the success payments liability associated with the Company's realization of a certain valuation threshold, were as follows:

	At September 30, 2022	At December 31, 2021
Fair value of common stock (per share)	\$ 34.35	\$ 36.87
Equity volatility	87 %	77 %

In February 2021, the Company provided written notice to Broad of its election to terminate the Broad License Agreement, which termination became effective in June 2021.

The reconciliation of changes in the fair value of financial instruments based on Level 3 inputs for the nine months ended September 30, 2022 is as follows:

(in thousands)	Success payment liability
Balance at December 31, 2021	\$ 4,371
Changes in fair value	691
Balance at September 30, 2022	\$ 5,062

The reconciliation of changes in the fair value of financial instruments based on Level 3 inputs for the nine months ended September 30, 2021 is as follows:

(in thousands)	Antidilution rights liability	Success payment liability	Total
Balance at December 31, 2020	\$ 6,916	\$ 2,806	\$ 9,722
Issuance of common stock	(32,490)	-	(32,490)
Changes in fair value	25,574	8,954	34,528
Balance at September 30, 2021	\$ -	\$ 11,760	\$ 11,760

6. Accrued expenses

Accrued expenses consist of the following:

(in thousands)	September 30, 2022	December 31, 2021
Accrued external research and development expenses	\$ 8,543	\$ 5,041
Employee compensation and related benefits	6,305	6,050
License and milestone payments	310	_
Professional fees	1,882	1,109
Other	2,609	792
Total	\$ 19.649	\$ 12.992

7. Leases

The Company's operating lease activity is comprised of non-cancelable facility leases for office and laboratory space in Cambridge, Massachusetts and Boston, Massachusetts.

The Company has also entered into multiple contract research and contract manufacturing service agreements with third parties which contain embedded leases within the scope of ASC 842. The embedded leases are considered short term leases, as the contractual terms are 12 months or less. Accordingly, no lease liability or ROU asset has been recorded. The Company has recognized \$0.2 million and \$0.6 million of short-term lease costs associated with the embedded leases during the three and nine months ended September 30, 2022, respectively. The Company recognized \$0.5 million and \$1.7 million of short-term lease costs associated with the embedded leases during the three and nine months ended September 30, 2021, respectively.

The components of operating lease cost were as follows:

	Three months ended September 30,				Nine	 s ended mber 30,
(in thousands)		2022		2021	2022	2021
Operating lease costs	\$	1,356	\$	495	\$ 2,366	\$ 1,418
Variable lease costs		428		187	885	530
Total	\$	1,784	\$	682	\$ 3,251	\$ 1,948

Supplemental cash flow information related to operating leases was as follows:

	Nine months e	nded	September 30,
(in thousands)	 2022		2021
Cash paid for amounts included in the measurements of lease liabilities:			
Operating cash flows related to operating leases	\$ 2,898	\$	1,492

As of September 30, 2022, the Company's operating leases were measured using a weighted-average incremental borrowing rate of 7.89% over a weighted-average remaining lease term of 10.3 years. As of September 30, 2021, the Company's operating leases were measured using a weighted-average incremental borrowing rate of 1.57% over a weighted-average remaining lease term of 1.2 years.

On August 19, 2021, the Company entered into a lease agreement with ARE-MA Region No. 87 Tenant, LLC, a Delaware limited liability company (the "Landlord"), pursuant to which the Company will lease approximately 104,933 square feet of office and laboratory space located at 201 Brookline Avenue, Boston, Massachusetts (the "Boston Lease"), further amended in January 2022 to include an additional 249 square feet, for a total of 105,182 square feet (the "Premises"). In June 2022, the Company entered into a second amendment to specify separate target commencement dates for certain areas of the Premises.

The Premises were first made available to the Company during the quarter ended September 30, 2022, and therefore the Boston Lease commenced during such quarter. Upon commencement of the lease, the Company recorded an operating lease ROU asset of \$91.8 million and a total lease liability of \$80.8 million.

The Company's obligation for the payment of base rent for the Premises begins in January 2023 (the "Rent Commencement Date"). Base rent will initially be \$0.8 million per month, which will increase by approximately 3% per annum.

The Boston Lease has a term of 10 years, measured from the Rent Commencement Date. The Company has the option to extend the term of the Boston Lease for a period of an additional five years. Under the terms of the Boston Lease, the Landlord has agreed to make up to \$21.0 million in certain tenant improvements to the Premises to suit the Company's use (the "Tenant Improvement Allowance"), which amount is included in the base rent set forth in the Boston Lease.

In connection with its entry into the Boston Lease and as a security deposit, the Company has provided the Landlord a letter of credit in the amount of approximately \$4.8 million, which may be reduced to approximately \$3.5 million on the expiration of the 36-month anniversary of the Rent Commencement Date so long as there are, and have been, no defaults by the Company under the terms of the Boston Lease. The Company also paid a deposit in the amount of \$0.8 million, which is equal to the first month of base rent. The Landlord has the right to terminate the Boston Lease upon customary events of default.

In anticipation of its move into the Boston Lease, in July 2022 the Company notified its landlord under the prior lease of its intent to terminate the prior lease prior to the expiration of the term lease. As of September 30, 2022, there was no remaining ROU and lease liability for the prior lease.

In October 2021, the Company entered into a sublease for 11,931 square feet of office and laboratory space in Cambridge, Massachusetts. The sublease commenced in December 2021 and has an initial noncancelable term of 12 months. The Company had the option to extend the sublease for one extension term of three months by written notice not less than six months prior to the expiration of the sublease term. The Company did not exercise this option. Therefore, this sublease is treated as a short-term lease. The total fixed lease payments over the sublease term are approximately \$1.4 million and the Company is also required to pay its proportional share of operating expenses.

Future minimum commitments under non-cancellable leases as of September 30, 2022 were as follows:

Years ending December 31,	Amount
	(in thousands)
Remainder of 2022	\$ 2,237
2023	9,868
2024	10,563
2025	10,868
2026	11,183
Thereafter	74,242
Total lease payments	\$ 118,961
Less: interest	(38,760)
Present value of operating lease liabilities	\$ 80,201

8. License agreements

The Company's significant license agreements are disclosed in Note 8, "License agreements," in the audited consolidated financial statements for the year ended December 31, 2021, and notes thereto, included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2022. Since the date of those financial statements, there have been no changes to its license agreements, except as noted below.

Harvard/Broad license agreement and Broad license agreement

In March 2019, the Company simultaneously entered into the Harvard/Broad License Agreement and Broad License Agreement (the "license agreements") for certain base editing technologies pursuant to which the Company received exclusive, worldwide, sublicensable, royalty-bearing licenses under specified patent rights to develop and commercialize licensed products and nonexclusive, worldwide, sublicensable, royalty-bearing licenses under certain patent rights to research and develop licensed products. The Company agreed to use commercially reasonable efforts to develop licensed products in accordance with the development plans, to introduce any licensed products that gain regulatory approval into the commercial market, to market licensed products that have gained regulatory approval following such introduction into the market, and to make licensed products that have gained regulatory approval reasonably available to the public. The term of the agreements will continue until the expiration of the last to expire valid claim. The Company may terminate either of the license agreements without cause upon four months' prior written notice to Harvard and Broad, unless terminated earlier. In February 2021, the Company provided written notice to Broad of its intent to terminate the Broad License Agreement, which termination was effective in June 2021.

As partial consideration for the rights granted under the Harvard/ Broad License Agreement and Broad License Agreement, the Company paid \$0.3 million in non-refundable upfront license fees and also issued 276,075 shares of its common stock with a fair value of \$0.3 million. Additional consideration under the license agreements is as follows:

Antidilution Rights—The initial shares of common stock issued to Harvard and Broad were subject to antidilution provisions as further described in Note 5, "Fair value of financial instruments." The antidilution rights associated with the Company achieving a defined aggregate level of preferred stock financing were partially satisfied in 2019 and fully satisfied in 2020, which settlement amounts totaled \$0.1 million and \$0.5 million, respectively, and which amounts were settled through issuances of 121,411 and 187,867 shares of common stock, respectively. The remaining antidilution rights obligation was fully satisfied in the three months ended June 30, 2021 with the Company's IPO. The settlement amount totaled \$32.5 million, and was settled through issuance of 878,098 shares of common stock.

Success Payments—The Company is required to make success payments under the license agreements as further described in Note 5, "Fair value of financial instruments." In September 2021, certain success payments were triggered and amounts due to Harvard and Broad totaled \$6.3 million. These amounts were settled in cash in November 2021.

Other Payments—The Company agreed to pay an annual license maintenance fee ranging from low-to-mid five figures to low six figures, depending on the particular calendar year, for each of the license agreements. The Company is responsible for the payment of certain patent prosecution and maintenance costs incurred by Harvard and Broad related to licensed patents. To the extent achieved, the Company is obligated to pay up to an aggregate of \$46.2 million and \$108 million in development and sales-based milestones, respectively. During the three months ended March 31, 2022, the first milestone was triggered and amounts due to Harvard and Broad totaled \$0.3 million. These amounts remain payable as of September 30, 2022 and will be settled in cash. If the Company undergoes a change of control during the term of the license agreements, then certain of the milestone payments would be increased by a mid-double-digit percentage. To the extent there are sales of a licensed product, the Company is required to pay low single digit royalties on net sales, for each of the license agreements. The Company is entitled to certain reductions and offsets on these royalties with respect to a licensed product in a given country.

Beam license agreement

In April 2019, the Company and Beam Therapeutics, Inc. ("Beam") entered into a collaboration and license agreement (the "Beam Agreement"). Pursuant to the Beam Agreement, the Company received an exclusive, worldwide, sublicensable license under certain of Beam's base editing technology, gene editing, and delivery technologies to develop, make, use, offer for sale, sell and import base editing products and nuclease products using Beam's CRISPR associated protein 12b, or Cas12b technology, in each case, directed to any of four initial gene targets, including the PCSK9 and ANGPTL3 genes, that are associated with an increased risk of coronary diseases. In addition, the Company granted Beam an exclusive, worldwide, sublicensable license under certain of its delivery technology to develop, manufacture, sell and import product candidates and products, except for base editor products licensed to Verve.

Both parties may conduct certain activities in accordance with an agreed-upon research and/or development plan. Following the dosing of the final patient in a Phase 1 clinical trial of a given licensed product for the initial gene targets, Beam has the right to opt in to share 33% of worldwide expenses of the development of such licensed product, as well as jointly commercialize and share profits and expenses of commercializing such licensed product in the United States on a 50/50 basis. If Beam exercises its opt-in right for a given licensed product for the initial gene targets, which we refer to following such opt-in as a collaboration product, it will be obligated to pay for a specified percentage of the development and commercialization costs of such collaboration product and will have the right to receive a specified percentage of the profits from any sales of such collaboration product. The term of the Beam Agreement continues until the last to expire of any royalty term for any product. The Company has the right to terminate the Beam Agreement as to any licensed product, but not for any collaboration product, by delivering a 90-day termination notice to Beam, provided that Beam has elected not to exercise its opt-in right or the period to exercise such opt-in right has expired. The Company is responsible for all costs and expenses incurred in the conduct of activities under the research plan, any development plan and any costs and expenses for the development of a licensed product for which Beam has not elected to opt-in.

As partial consideration for the license rights granted by Beam under the Beam Agreement, the Company paid a one-time, nonrefundable fee through issuing 276,075 shares of its common stock with a fair value of \$0.3 million. To the extent achieved, for each licensed product, the Company is also obligated to pay up to \$11.3 million in development and regulatory-based milestones and \$15.0 million in sales-based milestones. To the extent there are sales of a licensed product, the Company is required to pay low-to-mid single digit royalties on net sales. To the extent achieved, for each collaboration product outside of the United States, the Company is obligated to pay up to \$5.6 million in development and regulatory-based milestones and \$7.5 million in sales-based milestones. To the extent there are ex-U.S. sales of a collaboration product, the Company is required to pay low-to-mid single digit royalties on net sales. Due to the submission of the Company's CTA in New Zealand, a milestone payment of \$0.3 million was triggered during the period ended June 30, 2022 and subsequently paid by the Company to Beam during the period ended September 30, 2022. Additionally, due to the first patient dosing with VERVE-101 in a clinical trial, a milestone payment of \$0.2 million was triggered and paid by the Company to Beam during the period ended September 30, 2022.

On July 5, 2022, the Company entered into an Amended and Restated Collaboration and License Agreement with Beam (the "Amended Beam Agreement").

Pursuant to the Amended Beam Agreement, Beam granted the Company an exclusive, worldwide, sublicensable license under certain of Beam's base editing technology to develop and commercialize products directed towards an additional liver-mediated, cardiovascular disease target. The Company is responsible for the development and commercialization of products targeting the additional gene target, subject to Beam's opt-in right. Following the dosing of the final patient in a Phase 1 clinical trial of a licensed product for such additional gene target, Beam has the right to opt-in to share 35% of worldwide expenses of the development of such licensed product, as well as jointly commercialize and share 35% of the profits and expenses of commercializing such licensed product worldwide. If Beam does not elect to opt-in, Beam is entitled to receive milestones and royalties on the same basis as other collaboration products as provided in the Beam Agreement.

In exchange, the Company granted to Beam an exclusive, worldwide, sublicensable, fully paid-up license under the Company's intellectual property, including under the Company's GalNAc-LNP delivery technology, relating to a preclinical program developed by the Company.

The Amended Beam Agreement also clarified intellectual property rights with respect to the Company's GalNAc-LNP delivery technology; grants Beam, on a target-by-target basis, the option to obtain a non-exclusive, worldwide, sublicensable license to the Company's GalNAc-LNP delivery technology for the development and commercialization of certain base editor products, as to which Beam would owe the Company a fee upon exercise of each option, certain regulatory and commercial sale milestones as well as low single-digit royalties on net sales for base editor products using the GalNAc-LNP delivery technology; terminates the Company's rights and economic obligations under the Beam Agreement with respect to the undisclosed genes, allowing the Company and Beam to independently develop and commercialize products directed to such gene targets; and concludes other licenses that applied under the Beam

Agreement with respect to delivery and other technologies developed by the parties for the development and commercialization of base editor products.

To the extent there are sales of a delivery technology product, each party will pay the other party low-to-mid single digit royalties based on the annual aggregate worldwide net sales resulting from the sale of each delivery technology product of such paying party; provided, however, that such royalty payments will not apply to net sales of the collaboration products or licensed products. The Company concluded the receipt of any milestone or royalty payments under the Beam Agreement was not probable as of September 30, 2022.

Beam materials exchange letter agreement

In October 2020, the Company and Beam entered into a materials exchange agreement wherein the parties agreed that Beam would provide certain mRNA, gRNA, and protein to the Company and that the Company would provide certain gRNAs to Beam at an agreed upon price per each material provided.

For the three and nine months ended September 30, 2022 and 2021, the Company did not purchase any materials from Beam.

For the three and nine months ended September 30, 2022, the Company recognized \$0.4 million as a reduction to research and development expense related to reimbursements received for materials sold to Beam. For the three and nine months ended September 30, 2021, the Company recognized \$0.0 million and \$0.2 million, respectively, as a reduction to research and development expense related to reimbursements received for materials sold to Beam.

Acuitas agreements

Development and option agreement

In December 2019, the Company and Acuitas Therapeutics, Inc. ("Acuitas") entered into a development and collaboration agreement, which agreement was amended and restated in October 2020. The Company agreed to reimburse Acuitas on a quarterly basis for its services performed related to the program activities based on an agreed upon number of fulltime employees committed to work on the program at an annual rate per employee, including reimbursement of reasonable external costs. The Company recognized research and development expense of approximately \$0.1 million during the three and nine months ended September 30, 2022, and \$0.1 million and \$0.7 million for the three and nine months ended September 30, 2021, respectively, related to the reimbursement of research and development services provided by Acuitas and technology maintenance fees.

License agreement

In October 2020, the Company paid Acuitas a non-refundable, upfront license fee of \$2.0 million (less a previously paid target reservation fee) to exercise an option with respect to a licensed product and a licensed genome target and entered into a non-exclusive, worldwide license with Acuitas, with a right to sub-license through multiple tiers, under the licensed LNP technology to research, develop and commercialize the licensed products using the LNP technology in connection with the PCSK9 gene target for all human therapeutic or prophylactic uses.

To the extent achieved, the Company is also obligated to pay up to an aggregate of \$9.8 million in clinical and regulatory milestones and \$9.5 million in sales-based milestones. Due to the first patient dosing, a milestone payment of \$0.8 million was triggered and paid during the period ended September 30, 2022.

Novartis license agreement

In October 2021, the Company entered into a license agreement with Novartis Pharma AG ("Novartis") to obtain a non-exclusive license to lipid technology the Company is using in connection with the research and development of certain product candidates, including VERVE-201. As consideration for the license and rights granted under the agreement, the Company made a one-time, non-refundable, upfront payment of \$0.8 million during the three months ended December 31, 2021. The license agreement requires the Company to pay up to an aggregate of \$10.0 million in clinical and regulatory milestones and \$35.0 million in sales-based milestones for products that incorporate the licensed lipid technology. The milestones have not been achieved and no expense has been recorded for these milestones as of September 30, 2022.

In June 2022, the Company amended the agreement to include three additional licensed products to the scope of the non-exclusive license. In consideration of the additional licensed products, the Company was required to make a one-time, non-refundable upfront payment of \$2.8 million to Novartis. This amount was recorded to research and development expense and was paid during the period ended September 30, 2022.

9. Collaboration and License Agreements

Vertex Agreement

Summary of Agreement

On July 18, 2022, the Company entered into the Vertex Agreement with Vertex for an exclusive, four-year worldwide research collaboration focused on developing *in vivo* gene editing candidates toward an undisclosed target for the treatment of a single liver disease. Additionally, the Company entered into the Stock Purchase Agreement with Vertex, pursuant to which the Company agreed to sell and issue 1,519,756 shares of its common stock to Vertex at a price of \$23.03 per share, for an aggregate purchase price of \$35.0 million. The sale of the common stock closed on July 20, 2022.

Pursuant to the Vertex Agreement, the Company is responsible for discovery, research and certain preclinical development of novel *in vivo* gene editing development candidates for the target of interest. The Company's research activities are focused on (i) identifying and engineering specific gene editing systems and *in vivo* delivery systems directed to the target and (ii) evaluating and optimizing development candidates to achieve criteria specified in the Collaboration Agreement. Vertex is obligated to reimburse the Company's research expenses consistent with a mutually agreed-upon research plan and budget ("Research Plan"). The research term has an initial term of four years and may be extended by Vertex for up to one additional year ("Research Term"). The Research Plan is overseen by a Joint Research Committee ("JRC") as detailed in the Collaboration Agreement. Any material amendments to the Research Plan are required to be mutually agreed to by the JRC.

During the Research Plan, Vertex may select certain gene editing systems and *in vivo* delivery systems directed at the target to become a licensed agent. Upon the designation of the licensed agent, Vertex shall receive a license to exploit the licensed agent, and the licensed agent will continue to be developed under the Research Plan in order to achieve certain development candidate criteria agreed to by the JRC. Following the Research Term, Vertex will be solely responsible for subsequent development, manufacturing and commercialization of any product candidate resulting from the licensed agent.

The Company received an upfront payment from Vertex of \$25 million and is eligible to receive (i) success payments of up to \$22 million for each product candidate (up to a maximum of \$66 million) that achieves the applicable development criteria and (ii) up to an aggregate of \$175 million in development milestones and (iii) up to an aggregate \$165 million in commercial milestone payments. The Company is also eligible to receive tiered single-digit royalties on net sales, with the rate dependent upon the type of product and subject to specified reductions. Such royalty payments will terminate on a country-by-country and product-by-product basis upon the later to occur of (i) the expiration of the last to expire valid claim under the patent rights covering such product in such country, (ii) the period of regulatory exclusivity associated with such product in such country or (iii) ten years after the first commercial sale of such product in such country.

Prior to the first patient dosing of the first Phase 1 clinical trial for the first product candidate developed under the Vertex Agreement, the Company also has the right to opt-in to a profit share arrangement pursuant to which Vertex and the Company would share the costs and net profits for all product candidates emerging from the collaboration. If the Company exercises its opt-in right, in lieu of milestones and royalties, it will be obligated to pay for a specified percentage of the development and commercialization costs, and it will have the right to receive a specified percentage of the profits from any sales of any product candidates advanced under the collaboration. At the time the Company exercises the option, it may elect a profit/cost share of up to 40% (with Vertex retaining a minimum of 60%). In order to exercise its opt-in right, the Company is required to pay a fee ranging from \$25 million to \$70 million, depending on the profit/cost percentage elected by the Company and the Company's licensed technology included in the most advanced product candidate at the time it exercises its opt-in right. Under all profit share scenarios, Vertex will control the worldwide development and commercialization of any product candidates resulting from the collaboration.

The Vertex Agreement includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature. The Company and Vertex each have the right to terminate the agreement for material breach by, or insolvency of, the other party following notice, and if applicable, a cure period. Vertex may also terminate the Vertex Agreement in its entirety for convenience upon 90 days' notice.

Accounting Analysis

The Company assessed the promised goods and services under the Vertex Agreement, in accordance with ASC 606. At inception, the Vertex Agreement included the following performance obligations: (i) the research services obligation which relates to the research and development services to be provided under the Research Plan (the "Research Services") and (ii) three Licensed Agent Material Rights related to the options to obtain licenses to exploit a licensed agent, at a discount.

The Company identified \$20.0 million of fixed transaction price consisting of the \$25.0 million upfront fee offset by a discount of \$5.0 million related to the 1,519,756 shares sold to Vertex under the Stock Purchase Agreement when measured at fair value on the date of issuance. The Company is also entitled to reimbursement of costs incurred associated with the delivery of services under the Research Plan. The Company utilized the most likely amount approach and estimated the expected cost reimbursement to be \$5.8 million at inception. The Company concluded that these amounts do not require a constraint and are included in the transaction price at inception. The Company considers this estimate at each reporting date and updates the estimate based on information available. As of September 30, 2022, the estimate of the expected reimbursement is \$5.8 million based on expectations as of such date. Additional consideration to be paid to the Company upon reaching certain milestones are excluded from the transaction price as that consideration may only be earned subsequent to an option exercise.

The Company has concluded that the variable consideration related to the cost reimbursement of the Research Services obligation will be allocated entirely to that obligation as the cost reimbursement relates specifically to the services being performed under the Research Plan. The reimbursement of Research Services is considered to be at a market rate and therefore depicts the estimated amount it would expect to receive for this obligation. As a result, the Company allocated the fixed consideration of \$20.0 million to the three Licensed Agent Material Rights based on their relative standalone selling prices. The estimated standalone selling price for each material right was based on an adjusted market assessment approach. The Company concluded that the market would be willing to pay an equal amount for each Licensed Agent license on a standalone basis before being adjusted for the probability of the option becoming exercisable upon the successful completion of research activities to identify the Licensed Agents. The Company reached this conclusion after considering (i) the downstream economics including success fees, milestones and royalties related to each Licensed Agent being identical and (ii) all Licensed Agents are targeting the same gene. As such, based on the relative standalone selling price for each of the three material rights, the allocation of the transaction price to the separate performance obligations is as follows:

Performance obligation	Amount
	(in thousands)
Research services obligation	\$ 5,845
First licensed agent material right	6,667
Second licensed agent material right	6,667
Third licensed agent material right	6,666
Total	\$ 25,845

The amount allocated to the Research Services Obligation will be recognized on a proportional performance basis over the period of service using input-based measurements of total cost of research incurred to estimate proportion performed and remeasured at the end of each reporting period. The amount allocated to the Licensed Agent Material Rights was recorded as deferred revenue and will commence recognition upon exercise of each option or, if an option is never exercised, it will be recognized in full upon expiry of the Research Term.

During the three and nine months ended September 30, 2022, the Company recognized \$0.9 million of revenue associated with the Vertex Agreement related to research services performed during the period. As of September 30, 2022, the Company has recorded \$20.0 million as non-current deferred revenue.

Costs incurred relating to the Company's collaboration programs under the Vertex Agreement consist of internal and external research costs, which primarily include: salaries and benefits, and preclinical research studies. These costs are included in research and development expenses in the Company's condensed consolidated statements of operations during the three and nine months ended September 30, 2022.

10. Preferred and common stock

In January 2021, the Company issued 77,163,022 shares of Series B Preferred Stock at a price of \$1.2182 per share for gross proceeds of \$94.0 million. The Company incurred issuance costs in connection with this transaction of \$0.2 million.

In June 2021, the Company amended and restated its certificate of incorporation to authorize 5,000,000 shares of preferred stock, which shares of preferred stock are currently undesignated, and 200,000,000 shares of common stock, \$0.001 par value per share.

In June 2021, the Company completed its IPO, pursuant to which the Company issued and sold 16,141,157 shares of its common stock, including 2,105,368 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of \$19.00 per share, for aggregate gross proceeds of \$306.7 million. The Company

received approximately \$281.6 million in net proceeds, after deducting underwriting discounts and offering expenses payable by the Company.

Upon the closing of the IPO, all outstanding shares of the Company's preferred stock automatically converted into 27,720,923 shares of the Company's common stock.

In June 2021, the Company issued 878,098 shares of its common stock to Harvard and Broad as final settlement of its antidilution rights obligation.

In July 2022, in connection with the execution of the Vertex Agreement, the Company and Vertex also entered into the Stock Purchase Agreement for the sale and issuance of 1,519,756 shares of the Company's common stock to Vertex at a price of \$23.03 per share, which is equal to the five-day volume-weighted average share price as of July 15, 2022, for an aggregate purchase price of \$35.0 million.

In July 2022, the Company completed a follow-on public offering of common stock, pursuant to which the Company issued and sold 9,583,334 shares of its common stock, including 1,250,000 shares of its common stock sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of \$27.00 per share. The Company received net proceeds of approximately \$242.9 million after deducting underwriting discounts and offering expenses of approximately \$15.8 million.

During the three months ended September 30, 2022, the Company sold 216,930 shares of its common stock under the Sales Agreement for aggregate net proceeds of \$7.3 million, after deducting commissions and offering expenses payable by the Company.

The holders of common stock are entitled to one vote for each share of common stock.

11. Stock-based compensation

The 2018 Equity Incentive Plan, or the 2018 Plan, adopted by the board of directors in August 2018 provided for the grant of qualified incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock and restricted stock units to the Company's employees, officers, directors, advisors, and outside consultants for the issuance or purchase of shares of the Company's common stock. The maximum number of shares of common stock that were authorized for issuance under the 2018 Plan was 6,885,653.

In June 2021, the Company's board of directors adopted, and the Company's stockholders approved, the 2021 Stock Incentive Plan, or the 2021 Plan, which became effective on June 16, 2021. The 2021 Plan provides for grant of qualified and nonqualified stock options, stock appreciation rights, restricted and unrestricted stock and stock units, performance awards, and other share-based awards to the Company's employees, directors, advisors and outside consultants. Under the 2021 Plan, the number of shares of common stock initially reserved for issuance was the sum of: (1) 3,466,530; plus (2) the number of shares as was equal to the sum of (x) the number of shares of common stock reserved for issuance under the 2018 Plan that remained available for grant under the 2018 Plan on June 16, 2021 and (y) the number of shares of common stock subject to outstanding awards granted under the 2018 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year, commencing on January 1, 2022 and continuing until, and including, January 1, 2031, equal to the lesser of (i) 5% of the number of shares of common stock outstanding on such date and (ii) the number of shares of common stock determined by the Company's board of directors.

On January 1, 2022, 2,425,587 shares of the Company's common stock were added to the amount reserved for issuance under the 2021 Plan in accordance with the 2021 Plan described above. As of September 30, 2022, the Company had reserved 7,057,629 shares of the Company's common stock for issuance of equity awards, of which 3,315,775 shares remained available for future grant under the 2021 Plan. Upon effectiveness of the 2021 Plan, the Company ceased granting additional awards under the 2018 Plan.

Stock-based compensation expense recorded in the condensed consolidated statements of operations and comprehensive loss is as follows:

	Three months ended September 30,				_	ns ended ember 30,
(in thousands)	2022		2021		2022	2021
Research and development	\$ 3,216	\$	1,285	\$	8,637	\$ 2,306
General and administrative	2,704		1,008		7,136	2,008
Total stock-based compensation expense	\$ 5,920	\$	2,293	\$	15,773	\$ 4,314

Stock options

The following table provides a summary of stock option activity during the nine months ended September 30, 2022:

	Number of options	Weighted average exercise price per share	Weighted average remaining contractual life (in years)	Aggregate intrinsic value ⁽²⁾ (in thousands)
Outstanding at December 31, 2021	6,119,295	\$ 9.44		
Granted	2,324,850	28.02		
Exercised	(586,202)	2.96		
Forfeited	(302,849)	20.93		
Outstanding at September 30, 2022	7,555,094	\$ 15.28	8.4	\$ 149,809
Exercisable at September 30, 2022	2,261,038	\$ 5.64	7.7	\$ 65,691
Expected to vest after September 30, 2022 ⁽¹⁾	5,294,056	\$ 19.40	8.8	\$ 84,118

- (1) This represents the number of unvested options outstanding as of September 30, 2022 that are expected to vest in the future.
- (2) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that were in the money as of September 30, 2022.

As of September 30, 2022, there was \$64.8 million of unrecognized stock-based compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.7 years.

Restricted stock units

During the nine months ended September 30, 2022, the Company granted 609,550 restricted stock units under the 2021 Plan. These restricted stock units vest annually over a four-year period.

A summary of the status of and change in unvested restricted stock units as of September 30, 2022 was as follows:

	Shares	Weighted- average grant date fair value per share
Unvested restricted stock units as of December 31, 2021	32,000	\$ 36.58
Restricted stock units granted	609,550	\$ 21.83
Restricted stock units forfeited	(32,150)	\$ 25.21
Unvested restricted stock units as of September 30, 2022	609,400	\$ 22.43

As of September 30, 2022, there was \$12.2 million of unrecognized stock-based compensation expense related to restricted stock units that are expected to vest. These costs are expected to be recognized over a weighted-average remaining vesting period of approximately 3.7 years.

2021 Amended and Restated Employee Stock Purchase Plan

In June 2021, the board of directors adopted, and the Company's stockholders approved, the 2021 Employee Stock Purchase Plan, or the ESPP, as amended and restated, which became effective on June 16, 2021. The Company initially reserved 433,316 shares of common stock for sale under the ESPP. The aggregate number of shares reserved for sale under the ESPP increases automatically on the first day of each fiscal year commencing on January 1, 2022 through January 1, 2031, by the number of shares equal to the least of (a) 1,083,290 shares, (b) 1% of the total outstanding shares of common stock on such date, and (c) a number of shares as may be determined by the board of directors in any particular year. The first offering period under the ESPP commenced on June 16, 2021 and ended on December 13, 2021. On January 1, 2022, 485,117 shares of common stock were added to the amount reserved for sale under the ESPP. As of September 30, 2022, 844,918 shares remained available for issuance under the ESPP. The second offering period ended on May 31, 2022, for which offering period the Company issued 25,218 shares. The next offering period commenced on June 1, 2022 and will end on November 30, 2022.

12. Net loss per share attributable to common stockholders

The Company's potential dilutive securities, which include unvested restricted stock, unvested restricted stock units and common stock options, have been excluded from the computation of diluted net loss per share as the effects would be

anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at period end, from the computation of diluted net loss per share attributable to common stockholders for the period indicated because including them would have had an anti-dilutive effect:

	As of	As of September 30,		
	2022	2021		
Unvested restricted stock	_	136,908		
Unvested restricted stock units	609,400	_		
Outstanding options to purchase common stock	7,555,094	5,905,521		
Total	8,164,494	6,042,429		

13. Income taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets.

14. Related party transactions

An executive officer of Beam was a board member of the Company until August 2022. In October 2020, the Company and Beam entered into a materials exchange agreement wherein the parties agreed that Beam would provide certain mRNA, gRNA, and protein to the Company and that the Company would provide certain gRNAs to Beam at an agreed upon price per each material provided. For the three and nine months ended September 30, 2021, the Company recognized \$0.0 million and \$0.2 million, respectively, as a reduction to research and development expense related to reimbursements received for materials sold to Beam. For the three and nine months ended September 30, 2022, the Company recognized \$0.4 million as a reduction to research and development expense related to reimbursements received for materials sold to Beam.

In October 2021, the Company entered into a sublease agreement with Beam for laboratory and office space in Cambridge, Massachusetts. The sublease commenced in December 2021. Total expenses incurred under this sublease were \$0.5 million and \$1.4 million for the three and nine months ended September 30, 2022, respectively.

An executive of Broad was a board member of the Company until May 2021. In March 2019, the Company simultaneously entered into the Harvard/Broad License Agreement and Broad License Agreement for certain base editing technologies pursuant to which the Company received exclusive, worldwide, sublicensable, royalty-bearing licenses under specified patent rights to develop and commercialize licensed products and nonexclusive, worldwide, sublicensable, royalty-bearing licenses under certain patent rights to research and develop licensed products. Additional consideration under the license agreements include success payments. See Note 8, "License agreements."

15. Subsequent events

The Company evaluated all subsequent events and determined there are no material recognized or unrecognized subsequent events requiring disclosure, other than as indicated in Note 1, "Nature of business and basis of presentation", with respect to sales of the Company's stock under the Sales Agreement with Jefferies.

Item 2. Management's discussion and analysis of financial condition and results of operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 14, 2022. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed in "Risk Factors" in Part II, Item 1A. You should carefully read the section entitled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

Overview

We are a clinical-stage genetic medicines company pioneering a new approach to the care of cardiovascular disease, or CVD, transforming treatment from chronic management to single-course gene editing medicines. Despite advances in treatment over the last 50 years, CVD remains the leading cause of death worldwide. The current paradigm of chronic care is fragile—requiring rigorous patient adherence, extensive healthcare infrastructure and regular healthcare access—and leaves many patients without adequate care. Our goal is to disrupt the chronic care model for CVD by providing a new therapeutic approach with single-course *in vivo* gene editing treatments focused on addressing the root causes of this highly prevalent and life-threatening disease. Our initial two programs target PCSK9 and ANGPTL3, respectively, genes that have been extensively validated as targets for lowering blood lipids, such as low-density lipoprotein cholesterol, or LDL-C. We believe that editing these genes could potently and durably lower LDL-C throughout the lifetime of patients with or at risk for atherosclerotic cardiovascular disease, or ASCVD, the most common form of CVD.

Our approach leverages multiple breakthroughs in 21st century biomedicine—human genetic analysis, gene editing, messenger RNA, or mRNA, -based therapies and lipid nanoparticle, or LNP, delivery—to target genes that are predominantly expressed in the liver and disrupt the production of proteins that cause CVD. We are advancing a pipeline of single-course *in vivo* gene editing programs, each designed to mimic natural disease resistance mutations and turn off specific genes in order to lower blood lipids, thereby reducing the risk of ASCVD. We intend to initially develop these programs for the treatment of patients with familial hypercholesterolemia, or FH, a genetic disease that causes life-long severely elevated blood LDL-C, leading to increased risk of early-onset ASCVD. If our programs are successful in FH, we believe they could also provide a potential treatment for the broader population of patients with established ASCVD. Ultimately, we believe that these treatments could potentially be developed for administration to people at risk for ASCVD as a preventative measure similar to the way that certain vaccines offer long-term protection against infectious diseases.

We were incorporated in March 2018 and commenced operations shortly thereafter. Since our inception, we have devoted substantially all of our resources to building our gene editing and LNP technology and advancing development of our portfolio of programs, establishing and protecting our intellectual property, conducting research and development activities, organizing and staffing our company, business planning, raising capital and providing general and administrative support for these operations. To date, we have financed our operations primarily through the sales of our preferred stock and through the sale of our common stock in our initial public offering, or IPO, our follow-on public offering, and our at-the-market, or ATM, equity offering program, and through our strategic partnership with Vertex Pharmaceuticals Incorporated, or Vertex.

On June 21, 2021, we completed our IPO in which we issued and sold an aggregate of 16,141,157 shares of our common stock, including 2,105,368 shares of common stock sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a public offering price of \$19.00 per share, for aggregate net proceeds of \$281.6 million, after deducting underwriting discounts and offering expenses payable by us. Upon completion of the IPO, all 256,682,054 shares of outstanding convertible preferred stock automatically converted into 27,720,923 shares of common stock.

On July 18, 2022, we entered into a Strategic Collaboration and License Agreement, or the Vertex Agreement, with Vertex Pharmaceuticals Incorporated, or Vertex, for an exclusive, four-year worldwide research collaboration focused on developing *in vivo* gene editing candidates toward an undisclosed target for the treatment of a single liver disease. Pursuant to the Vertex Agreement, Vertex paid us \$25.0 million in an upfront payment on July 20, 2022. We are eligible to receive (i) success payments of up to \$22 million for each product candidate (up to a maximum of \$66 million) that achieves the applicable development criteria and (ii) up to an aggregate of \$340 million in development and commercial milestone payments. We are also eligible to receive tiered single-digit royalties on net sales, subject to specified reductions.

On July 18, 2022, in connection with the execution of the Vertex Agreement, we also entered into a stock purchase agreement with Vertex, or the Stock Purchase Agreement, for the sale and issuance of 1,519,756 shares of our common stock to Vertex at a price of \$23.03 per share, which is equal to the five-day volume-weighted average share price as of July 15, 2022, for an aggregate purchase price of \$35.0 million.

On July 25, 2022, we issued and sold 9,583,334 shares of our common stock, including an additional 1,250,000 shares of common stock sold pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, at a public offering price of \$27.00 per share, for aggregate net proceeds of approximately \$242.9 million after deducting underwriting discounts and expenses of approximately \$15.8 million payable by us.

On July 1, 2022, we entered into an Open Market Sale AgreementSM, or the Sales Agreement, with Jefferies LLC, or Jefferies, as the agent, pursuant to which we are entitled to offer and sell, from time to time at prevailing market rates, shares of our common stock. We agreed to pay Jefferies a commission of up to 3.0% of the aggregate gross sale proceeds of any shares sold by Jefferies under the Sales Agreement. Any sales under the Sales Agreement will be made pursuant to our registration statement on Form S-3 (File No 333-267578), which became effective on September 23, 2022, with an aggregate offering price of up to \$200.0 million. As of September 30, 2022, we had sold 216,930 shares of common stock under the Sales Agreement for aggregate net proceeds of \$7.3 million, after deducting commissions and offering expenses payable by us. After September 30, 2022, we sold an additional 1,063,238 shares of common stock under the Sales Agreement for aggregate net proceeds of \$36.0 million.

As of September 30, 2022, we had raised an aggregate of \$829.5 million in gross proceeds from the sale of our preferred and common stock in private placements and common stock to the public.

We are a clinical-stage company. To date, we have not generated any revenue from product sales and do not expect to generate revenue from the sale of products for the foreseeable future. Prior to the execution of the Vertex Agreement, on July 18, 2022, we had not recorded any revenue. Since our inception, we have incurred significant operating losses. Our net losses for the three and nine months ended September 30, 2022 were \$45.2 million and \$116.3 million, respectively. Our net losses for the three and nine months ended September 30, 2021 were \$22.7 million and \$89.0 million, respectively. As of September 30, 2022, we had an accumulated deficit of \$303.2 million.

We expect to continue to incur significant expenses and increasing operating losses in connection with ongoing development activities related to our portfolio of programs as we advance VERVE-101 in our ongoing heart-1 clinical trial; continue our preclinical development of other product candidates; advance these product candidates toward clinical development; further develop base editing and novel gene editing technology, delivery technology and manufacturing capabilities; seek to discover and develop additional product candidates including VERVE-201, our development candidate targeting ANGPTL3; maintain, expand enforcement, defend, and protect our intellectual property portfolio; hire research and development and clinical personnel; ultimately establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval; establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval; and add operational, legal, compliance, financial and management information systems and personnel to support our research, product development, future commercialization efforts and operations as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings and other sources of capital, which may include collaborations or licensing arrangements with other companies or other strategic transactions. If we are unable to raise capital or obtain adequate funds when needed or on acceptable terms, we may be required to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2022, we had cash, cash equivalents and marketable securities of \$550.7 million. We believe that our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2025. We have based this estimate on assumptions that may prove to be

wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. See "Liquidity and capital resources."

Recent Developments

VERVE-101

Our lead product candidate, VERVE-101, is designed to permanently turn off the PCSK9 gene in the liver. PCSK9 is a highly validated target that plays a critical role in controlling blood LDL-C through its regulation of the LDL receptor, or LDLR. Reduction of PCSK9 protein in the blood improves the ability of the liver to clear LDL-C from the blood. VERVE-101 utilizes LNP-mediated delivery to target the liver and base editing technology to make a single base change at a specific site in the PCSK9 gene in order to disrupt PCSK9 protein production.

VERVE-101 is being developed for the treatment of patients with heterozygous familial hypercholesterolemia, or HeFH, which affects approximately 1.3 million people in the United States and approximately 31 million worldwide. We are strategically developing VERVE-101 initially in patients with HeFH, recognizing that the unmet need is highest in those patients and the benefit-risk profile may be more favorable. We intend to use a stepwise clinical development plan for VERVE-101, evaluating efficacy and safety in higher-risk populations first, and then if successful, expanding into broader population of patients with established ASCVD who are not at LDL-C goal on oral therapy, and ultimately to those at risk for ASCVD in the general population.

In November 2022, we presented data from preclinical studies that evaluated the potential for VERVE-101 to edit germline cells or be passed on to offspring. In a study of six sexually mature male NHPs, sequencing of sperm samples before and after treatment with VERVE-101 showed no evidence of PCSK9 gene editing. In a study of 436 offspring of female mice treated with the murine surrogate of VERVE-101 genotyping of the offspring showed that the PCSK9 gene edit was not transmitted to any of the offspring.

Ongoing heart-1 clinical trial

In July 2022, we announced that the first patient has been dosed with VERVE-101 in our heart-1 clinical trial, which is a global Phase 1 open-label clinical trial. We are enrolling patients in New Zealand and the United Kingdom.

We submitted our investigational new drug, or IND, application to conduct a clinical trial evaluating VERVE-101 to the FDA in October, and on November 4, 2022, we were informed by the FDA that our IND was placed on hold. The FDA indicated they will provide a detailed hold letter to us within 30 days. We plan to provide updates pending engagement with the FDA, and we intend to work closely with the FDA to resolve the hold as promptly as possible in order to initiate dosing in the U.S.

The heart-1 trial is designed to enroll approximately 40 adult patients with HeFH who have established ASCVD and evaluate the safety and tolerability of VERVE-101 administration, with additional analyses for pharmacokinetics and reductions in blood PCSK9 protein and LDL-C. The trial includes three parts – (A) a single ascending dose portion, followed by (B) an expansion single-dose cohort, in which additional participants will receive the selected potentially therapeutic dose and (C) an optional second-dose cohort, in which eligible participants in lower dose cohorts in Part A have the option to receive a second treatment at the selected potentially therapeutic dose. During our interactions with regulators in New Zealand and the United Kingdom, country-specific protocols have been developed to account for various modifications to eligibility, design, and conduct in each country.

Clinical data from the ongoing heart-1 study in New Zealand and the U.K. were not included in the IND application package submitted to the FDA. We have completed dosing of VERVE-101 in the first dose cohort of the dose-escalation portion of the heart-1 trial, which was well tolerated in all three patients. There have been no treatment-related adverse events reported to date, and all adverse events observed have been Grade 1 in nature. The independent Data Safety Monitoring Board, or DSMB, has reviewed safety data from the first cohort and recommended dose escalation to the planned second dose level, which is expected to begin soon. Enrollment efforts are ongoing in New Zealand and the U.K. We plan to report initial safety and pharmacodynamic data for all dose cohorts of the dose-escalation portion of the heart-1 study at a medical meeting in the second half of 2023.

VERVE-201

VERVE-201, our development candidate targeting ANGPTL3, is designed to permanently turn off the ANGPTL3 gene in the liver. We plan to develop this program initially for the treatment of homozygous familial hypercholesterolemia, or HoFH, which affects approximately 1,300 patients in the United States. Similar to our approach with VERVE-101, we plan to expand the clinical development of VERVE-201 in a stepwise fashion beyond HoFH to patients with established ASCVD who may need additional LDL-C and/or triglycerides reduction. Ultimately, we believe that VERVE-201 may also

be useful to people at risk for ASCVD as a preventative measure in the general population. We have initiated IND-enabling studies for VERVE-201.

We plan to utilize internally developed GalNAc-LNP technology in VERVE-201 to deliver a base editor targeting the ANGPTL3 gene to the liver. In patients with HoFH, delivery of base editors with standard LNPs to the liver is challenging due to the deficiency of LDLR, which is known to mediate LNP uptake. We have developed proprietary LNPs with a GalNAc ligand designed to bind to asialoglycoprotein receptors, in the liver, which bypass LDLR, thereby enabling uptake into the liver in HoFH patients.

Prior to nominating VERVE-201 as a product candidate, we used a rigorous process designed to optimize preclinical safety and efficacy. We selected an optimized configuration and evaluated VERVE-201 in primary human liver cells, which showed potent, on-target editing of the ANGPTL3 gene with no detectable off-target and no detectable structural variants as assessed using high-coverage whole genome optical mapping.

We believe our data generated to date suggests that GalNAc-LNP delivery may have broad utility for liver editing in other indications.

We are continuing to invest and build out capabilities in the development of novel and optimized GalNAc-targeting ligands, optimal lipid anchors, optimal compositions and ratios of LNP components, and optimal processes of addition and LNP formation with targeting ligands. We believe GalNAc provides a delivery platform for patients with both forms of FH and potentially may be applicable in other applications where liver-directed delivery is advantageous.

Impact of COVID-19 on our business

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization and to date, the COVID-19 pandemic continues to present a substantial public health and economic challenge around the world. The length of time and full extent to which the COVID-19 pandemic may directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain, subject to change and difficult to predict. We, our contract manufacturing organizations, or CMOs, and our contract research organizations, or CROs, experienced temporary reductions in the capacity to undertake research-scale production and to execute some preclinical studies. While these operations have since normalized, we, together with our CMOs and CROs, continue to closely monitor the impact of the COVID-19 pandemic on these operations.

We also plan to continue to closely monitor the ongoing impact of the COVID-19 pandemic on our employees and our other business operations. In an effort to provide a safe work environment for our employees, we have, among other things, limited employees in our office and lab facilities to those where on-site presence is needed for their job activities, increased the cadence of sanitization of our office and lab facilities, implemented various social distancing measures in our offices and labs including replacing all in-person meetings with virtual interactions. Recently, additional employees have returned to our office and lab facilities in limited capacities. We continue to provide personal protective equipment and recommend regular COVID-19 testing for employees and visitors present in our office and lab facilities. We continue to monitor the impact and effects of the COVID-19 pandemic and our response to it, and we expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners in light of the pandemic.

While the COVID-19 pandemic did not significantly impact our business or results for the three and nine months ended September 30, 2022 and 2021, the length and extent of the pandemic, its consequences, and containment efforts will determine the future impact on our operations and financial condition.

License and collaboration agreements

We have obligations under various license and collaboration agreements to make potentially significant milestone and success payments in the future and to pay royalties on sales of any product candidates covered by those agreements that eventually achieve regulatory approval and commercialization. For information regarding these agreements, see Note 8, "License agreements" and Note 9, "Collaboration and license agreements" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Components of our results of operations

Revenue

During the three and nine months ended September 30, 2022 we recognized \$0.9 million in collaboration revenue. We do not expect to generate any revenue from the sale of products in the near future and unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. If our development efforts for our product candidates are successfully enter into license or

collaboration agreements with third parties, in addition to the Vertex Agreement, we may generate revenue in the future from product sales, payments from such additional third-party collaboration or license agreements, or any combination thereof.

Operating expenses

Research and development expenses

Research and development expenses consist of costs incurred in performing research and development activities, which include:

- the cost to obtain and maintain licenses to intellectual property, such as those with the President and Fellows of Harvard College, or Harvard, The Broad Institute, Inc., or Broad, Beam Therapeutics Inc., or Beam, Acuitas Therapeutics, Inc., or Acuitas, and Novartis Pharma AG, or Novartis, and related future payments should certain development and regulatory milestones be achieved;
- personnel-related expenses, including salaries, bonuses, benefits and stock-based compensation for employees engaged in research and development functions;
- expenses incurred in connection with the discovery and preclinical development of our research programs, including under agreements with third parties, such as consultants, contractors and CROs;
- the cost of developing and validating our manufacturing process for use in our preclinical studies and ongoing, planned and future clinical trials, including the cost of raw materials used in our research and development activities;
- · the cost of laboratory supplies and research materials; and
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance.

We expense research and development costs as incurred. Nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the benefits are consumed.

In the early phases of development, our research and development costs are often devoted to proof-of-concept studies that are not necessarily allocable to a specific target; therefore, we have not yet begun tracking our expenses on a program-by-program basis.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we advance our programs and product candidates into and through clinical development, as we continue to develop additional product candidates, as we continue to build our manufacturing capabilities, and as we continue to develop our gene editing and LNP technology. We also expect our discovery research efforts and our related personnel costs will increase and, as a result, we expect our research and development expenses, including costs associated with stock-based compensation, will increase above historical levels. In addition, we may incur additional expenses related to milestone and royalty payments payable to third parties with whom we may enter into license, acquisition and option agreements to acquire the rights to future product candidates.

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of, and obtain regulatory approval for, any of our product candidates or programs. The successful development of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development, including the following:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- · raising additional funds necessary to complete preclinical and clinical development of our product candidates;
- the timing of filing and acceptance of INDs or comparable foreign applications that allow commencement of planned and future clinical trials for our product candidates;
- the successful initiation, enrollment and completion of clinical trials;
- our ability to achieve positive results from our ongoing and future clinical programs that support a finding of safety and effectiveness and an acceptable risk-benefit profile in the intended patient populations of any product candidates we may develop;

- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, our product candidates for the
 expected indications and patient populations;
- our ability to hire and retain key research and development personnel;
- the costs associated with the development of any additional product candidates we develop or acquire through collaborations;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidates are approved:
- the terms and timing of any existing or future collaboration, license or other arrangement, including the terms and timing of any milestone
 payments thereunder;
- our ability to establish and obtain intellectual property protection and regulatory exclusivity for our product candidates and enforce and defend our intellectual property rights and claims;
- · our ability to commercialize products, if and when approved, whether alone or in collaboration with others;
- our ability to maintain a continued acceptable safety, tolerability and efficacy profile of our product candidates following approval; and
- the effects of the COVID-19 pandemic.

A change in any of these variables with respect to any of our current or future product candidates could significantly change the costs, timing and viability associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any product candidate we may develop.

General and administrative expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, benefits and stock-based compensation, for personnel in our executive, intellectual property, business development, and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters, professional fees for accounting, auditing, tax and consulting services, insurance costs, travel, and direct and allocated facility-related expenses and other operating costs.

We anticipate that our general and administrative expenses will increase in the future to support increased research and development activities. We also expect to continue to incur increased costs associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Other income

Change in fair value of antidilution rights liability

Change in fair value of antidilution rights liability consists of remeasurement gains or losses associated with changes in the antidilution rights liability associated with our license agreements with Harvard and Broad, or the Harvard/Broad License Agreement, and Broad, or the Broad License Agreement.

The antidilution rights represented the obligation to issue additional shares of common stock to Harvard and Broad following the completion of preferred stock financings and other equity financings, which was fully satisfied upon the closing of our IPO. At the inception of the agreements, the liability for the antidilution rights was recorded at fair value with the cost recorded as research and development expense and were remeasured at each reporting period with changes recorded in other income (expense) while the instruments are outstanding.

The antidilution rights liability was partially satisfied in 2019 and 2020 and was satisfied in full in June 2021 upon the closing of our IPO with the issuance of an additional 878,098 shares of our common stock.

Change in fair value of success payment liability

We are also obligated to pay to Harvard and Broad tiered success payments in the event our average market capitalization exceeds specified thresholds ascending from a high nine-digit dollar amount to \$10.0 billion, or sale of our company for consideration in excess of those thresholds. In the event of a change of control of our company or a sale of our company, we are required to pay any related success payment in cash within a specified period following such event. Otherwise, the success payments may be settled at our option in either cash or shares of our common stock, or a combination of cash and shares of our common stock. The maximum aggregate success payments that could be payable

by us are \$31.3 million. At inception of the agreements, the success payment liabilities were recorded at fair value with the cost recorded as research and development expense and are being remeasured at each reporting period with charges recorded in other income (expense) while the instrument is outstanding.

Depending on our valuation, the fair value of the success payment liability, and the corresponding changes in fair value that we record in our statements of operations, could fluctuate significantly from period to period.

During the year ended December 31, 2021, certain success payment obligations were triggered, and amounts due to Harvard and Broad totaled \$6.3 million. These amounts were settled in cash in November 2021. The remaining success payment obligations will continue to be revalued at the end of each reporting period.

Interest and other income, net

Interest and other income primarily consisted of interest earned on our marketable securities and other miscellaneous income and expenses unrelated to our core operations.

Income tax

During the three and nine months ended September 30, 2022 and 2021, we recorded a full valuation allowance on federal and state deferred tax assets since management does not forecast that we will be in a taxable position in the near future.

Results of operations

Comparison of three months ended September 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021:

		Three months ended September 30,				
(in thousands)	_	2022		2021		Change
Collaboration revenue	\$	929	\$	-	\$	929
Operating expenses:						
Research and development	\$	35,197	\$	17,495	\$	17,702
General and administrative		9,592		6,007		3,585
Total operating expenses	\$	44,789	\$	23,502	\$	21,287
Other (expense) income:						
Change in fair value of success payment liability		(3,306)		700		(4,006)
Interest and other income, net		1,976		53		1,923
Total other (expense) income	\$	(1,330)	\$	753	\$	(2,083)
Net loss	\$	(45,190)	\$	(22,749)	\$	(22,441)

Collaboration Revenue

Collaboration revenue was \$0.9 million for the three months ended September 30, 2022, all of which related to research services performed under the Vertex Agreement. We did not record any revenue for the three months ended September 30, 2021.

Research and development expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2022 and 2021:

	Three months ended September 30,						
(in thousands)	•	2022		2021		Change	
Employee-related expenses	\$	12,351	\$	5,505	\$	6,846	
External expenses associated with preclinical studies performed by outside consultants, including third-party CROs		7,595		4,770		2,825	
Raw material costs and external expenses associated with manufacturing activities, including third-party CMOs		5,842		3,962		1,880	
License and milestone payments		1,082		45		1,037	
Lab supplies		3,083		1,190		1,893	
Facility-related costs (including depreciation)		2,451		925		1,526	
Clinical trial costs		867		-		867	
Other research and development costs		1,926		1,098		828	
Total research and development expenses	\$	35,197	\$	17,495	\$	17,702	

Research and development expenses were \$35.2 million for the three months ended September 30, 2022, compared to \$17.5 million for the three months ended September 30, 2021. The increase of \$17.7 million was primarily due to the following:

- an increase in personnel-related costs of \$6.8 million, including an increase in stock-based compensation of \$1.9 million, driven by an increase in headcount of employees involved in research and development activities;
- an increase in external expenses associated with preclinical studies (primarily animal-study costs) performed by outside consultants, including third-party CROs, of \$2.8 million;
- an increase in raw material costs and external expenses associated with developing and validating our manufacturing activities, including third-party CMOs, for use in our preclinical studies and clinical trial of \$1.9 million;
- an increase in research and development expense attributed to license and milestone payments of \$1.0 million;
- an increase in lab supplies of \$1.9 million due to increased headcount and company growth;
- an increase in facility-related costs (including depreciation) and other allocated expenses of \$1.5 million due to increased investment in research and development as well as additional space leased at 201 Brookline Avenue;
- an increase in clinical trial costs of \$0.9 million associated with our heart-1 clinical trial, a Phase 1 clinical trial of VERVE-101; and
- an increase in other research and development costs of approximately \$0.9 million, primarily due to an increase in software, IT, and other miscellaneous charges.

We expect that our research and development expenses will continue to increase for the foreseeable future as we advance our programs and product candidates into and through clinical development, and as we continue to develop additional product candidates and invest in our technology and manufacturing capabilities.

General and administrative expenses

General and administrative expenses were \$9.6 million for the three months ended September 30, 2022, compared to \$6.0 million for the three months ended September 30, 2021. The increase of \$3.6 million was primarily attributable to the following:

 an increase of \$3.6 million in personnel, facility and other expenses, including stock-based compensation, resulting from an increase in headcount to support our growth; and

- an increase of \$0.6 million in legal and professional service fees, primarily due to increased professional fees for audit, tax and consulting services; partially offset by
- a decrease in other miscellaneous expenses of \$0.6 million, primarily due to decreases in software, IT, and other miscellaneous charges.

We anticipate that our general and administrative expenses will increase in the future to support increased research and development activities.

Other income (expense)

Change in fair value of success payments liability

During the three months ended September 30, 2022, the change in fair value of the success payments liability was primarily due to the increase in the fair value of our common stock, which resulted in \$3.3 million of other expense. During the three months ended September 30, 2021, the change in fair value for the success payments liability of \$0.7 million was primarily due to the decrease in the fair value of our common stock.

Interest and other income, net

The increase of \$1.9 million in interest and other income, net for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 was primarily attributable to increasing interest rates on marketable security balances.

Comparison of nine months ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021:

	Nine months ended September 30,				
(in thousands)	 2022		2021		Change
Collaboration revenue	\$ 929	\$	_	\$	929
Operating expenses:					
Research and development	\$ 92,811	\$	42,263	\$	50,548
General and administrative	26,095		12,264		13,831
Total operating expenses	\$ 118,906	\$	54,527	\$	64,379
Other income (expense):					
Change in fair value of antidilution rights liability	_		(25,574)		25,574
Change in fair value of success payment liability	(691)		(8,954)		8,263
Interest and other income, net	2,366		78		2,288
Total other income (expense)	\$ 1,675	\$	(34,450)	\$	36,125
Net loss	\$ (116,302)	\$	(88,977)	\$	(27,325)

Collaboration Revenue

Collaboration revenue was \$0.9 million for the nine months ended September 30, 2022, all of which related to the Vertex Agreement. We did not record any revenue for the nine months ended September 30, 2021.

Research and development expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2022 and 2021:

		Nine months ended September 30,					
(in thousands)		2022		2021		Change	
Employee-related expenses	\$	32,200	\$	12,311	\$	19,889	
External expenses associated with preclinical studies performed by outside consulting services, including third-party CROs		21,297		12,461		8,836	
Raw material costs and external expenses associated with manufacturing activities, including third-party CMOs		15.499		9,347		6,152	
Lab supplies		6,858		3,059		3,799	
License and milestone payments		4,483		125		4,358	
Facility-related costs (including depreciation)		5,482		2,525		2,957	
Clinical trial costs		2,184		-		2,184	
Other research and development costs		4,808		2,435		2,373	
Total research and development expenses	\$	92,811	\$	42,263	\$	50,548	

Research and development expenses were \$92.8 million for the nine months ended September 30, 2022, compared to \$42.3 million for the nine months ended September 30, 2021. The increase of \$50.5 million was primarily due to the following:

- an increase in personnel-related costs of \$19.9 million, including an increase in stock-based compensation of \$6.3 million, driven by an
 increase in headcount of employees involved in research and development activities;
- an increase in external expenses associated with preclinical studies (primarily animal-study costs) performed by outside consultants, including third-party CROs, of \$8.8 million;
- an increase in raw material costs and external expenses associated with developing and validating our manufacturing activities, including third-party CMOs, for use in our preclinical studies and clinical trial of \$6.2 million;
- an increase in lab supplies of \$3.8 million due to increased headcount and company growth;
- an increase in research and development expense attributed to license and milestone payments of approximately \$4.3 million in 2022;
- an increase in facility-related costs (including depreciation) and other allocated expenses of \$3.0 million due to increased investment in research and development as well as additional space leased at 201 Brookline Avenue;
- an increase in clinical trial costs of \$2.2 million associated with our heart-1 clinical trial, a Phase 1 clinical trial of VERVE-101; and
- an increase in other research and development costs of approximately \$2.3 million, primarily due to an increase in software, IT, and other miscellaneous charges.

General and administrative expenses

General and administrative expenses were \$26.1 million for the nine months ended September 30, 2022, compared to \$12.3 million for the nine months ended September 30, 2021. The increase of \$13.8 million was primarily attributable to the following:

- an increase of \$10.1 million in personnel, facility and other expenses, including stock-based compensation, resulting from an increase in headcount to support our growth;
- an increase of \$2.7 million in legal and professional service fees, primarily due to increased professional fees for audit, tax and consulting services; and
- an increase in other miscellaneous expenses of \$1.0 million, primarily due to increases in software, IT, and other miscellaneous charges.

Other income (expense)

Change in fair value of antidilution rights liability

The decrease in the change in the fair value of the antidilution rights liability was as a result of the liability being fully settled during the nine months ended September 30, 2021 with the issuance of 878,098 shares of our common stock.

Change in fair value of success payments liability

During the nine months ended September 30, 2022, the change in fair value of the success payments liability was primarily due to the increase in the fair value of our common stock, which resulted in expense of \$0.7 million to other expense. During the nine months ended September 30, 2021, the change in fair value for the success payments liability of \$9.0 million was primarily due to the increase in the fair value of our common stock.

Interest and other income, net

The increase of \$2.3 million in interest and other income, net for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 was primarily attributable to higher marketable securities balances and increasing interest rates.

Liquidity and capital resources

Sources of liquidity and capital

Since our inception in 2018, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and, if successful, clinical development of our programs. To date, we have funded our operations primarily through equity offerings. Through September 30, 2022, we had raised an aggregate of \$829.5 million in gross proceeds from sales of our preferred stock and common stock in private placements and common stock in our IPO, our follow-on public offering, and our ATM equity offering program. As of September 30, 2022, we had \$550.7 million in cash, cash equivalents and marketable securities.

In June 2021, we completed our IPO in which we issued 16,141,157 shares of our common stock, including 2,105,368 shares of common stock sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a public offering price of \$19.00 per share. We received net proceeds from our IPO of \$281.6 million, after deducting underwriting discounts and offering expenses payable by us. In June 2021, we issued 878,098 shares of our common stock to Harvard and Broad as final settlement of the antidilution rights liability.

On July 20, 2022, we received \$25.0 million as an upfront payment from Vertex pursuant to the Vertex Agreement. Additionally, on July 20, 2022, we sold and issued 1,519,756 shares of our common stock to Vertex in connection with the Private Placement at a price of \$23.03 per share for an aggregate purchase price of \$35.0 million.

On July 25, 2022, we issued and sold 9,583,334 shares of our common stock, including an additional 1,250,000 shares of common stock sold pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, at a public offering price of \$27.00 per share, for aggregate net proceeds of approximately \$242.9 million after deducting underwriting discounts and offering expenses of approximately \$15.8 million payable by us.

In July 2022, we entered into the Sales Agreement with Jefferies pursuant to which we are entitled to offer and sell, from time to time at prevailing market rates, shares of our common stock. We agreed to pay Jefferies a commission of up to 3.0% of the aggregate gross sale proceeds of any shares sold by Jefferies under the Sales Agreement. Any sales under the Sales Agreement will be made pursuant to our registration statement on Form S-3 (File No 333-267578), which became effective on September 23, 2022, with an aggregate offering price of up to \$200.0 million. In September 2022, we had sold 216,930 shares of common stock under the Sales Agreement for aggregate net proceeds of \$7.3 million, after deducting commissions and offering expenses payable by us. After September 30, 2022, we sold an additional 1,063,238 shares of common stock under the Sales Agreement for aggregate net proceeds of \$36.0 million, after deducting commissions and offering expenses payable by us.

Cash flows

The following table summarizes our sources and uses of cash for each period presented:

	Nine months ended September 30,					
(in thousands)	 2022		2021			
Cash used in operating activities	\$ (89,440)	\$	(49,837)			
Cash provided by (used in) investing activities	12,358		(182,113)			
Cash provided by financing activities	289,358		375,865			
Net increase in cash, cash equivalents and restricted cash	\$ 212,276	\$	143,915			

Operating activities

For the nine months ended September 30, 2022, net cash used in operating activities was \$89.4 million, consisting primarily of our net loss of \$116.3 million, partially offset by the following non-cash changes: \$0.7 million associated with the fair value change in success payments liability, stock-based compensation of \$15.8 million, depreciation expense of \$1.9 million, non-cash lease expense of \$2.3 million and amortization of investment premiums of \$1.1 million and changes in our operating assets and liabilities of \$5.1 million.

For the nine months ended September 30, 2021, net cash used in operating activities was \$49.8 million, consisting primarily of our net loss of \$89.0 million and a decrease in our operating assets and liabilities of \$2.9 million, partially offset by the following non-cash changes: \$25.6 million associated with the fair value change in antidilution rights liability, \$9.0 million associated with the fair value change in success payments liability, stock-based compensation of \$4.3 million, depreciation expense of \$1.1 million, non-cash lease expense of \$1.3 million and amortization of investment premiums of \$0.8 million.

Investing activities

For the nine months ended September 30, 2022, net cash provided by investing activities was \$12.4 million and consisted of maturities of marketable securities of \$242.7 million, partially offset by purchases of marketable securities of approximately \$222.0 million and purchases of property and equipment of \$8.3 million, primarily related to lab equipment.

For the nine months ended September 30, 2021, net cash used in investing activities was \$182.1 million and consisted of purchases of property and equipment of \$3.4 million, primarily related to lab equipment, and purchases of marketable securities of \$234.5 million, offset partially by maturities of marketable securities of \$55.8 million.

Financing activities

For the nine months ended September 30, 2022, net cash provided by financing activities was \$289.4 million, consisting primarily of net proceeds from the sale of our common stock of \$247.3 million, proceeds of \$40.0 million from the issuance of 1,519,756 shares to Vertex pursuant to the Stock Purchase Agreement in connection with the Vertex Agreement, proceeds from exercises of stock options of approximately \$1.8 million, and issuance of shares through our employee stock purchase plan of \$0.3 million.

For the nine months ended September 30, 2021, net cash provided by financing activities was \$375.9 million, consisting primarily of the net proceeds from the issuance of Series B Preferred Stock of \$93.8 million, net proceeds from the sale of our common stock in our IPO of \$281.6 million and proceeds from exercises of stock options of \$0.5 million.

Funding requirements

Our operating expenses and future funding requirements are expected to increase substantially as we continue to advance our portfolio of programs.

Specifically, our expenses will increase if and as we:

- conduct our ongoing heart-1 clinical trial for VERVE-101 in New Zealand and the United Kingdom, and if our IND application is cleared, in the United States:
- continue our current research programs and our preclinical development of product candidates from our current research programs;
- seek to identify additional research programs and additional product candidates;
- · advance our existing and future product candidates into clinical development;

- initiate preclinical studies and clinical trials for any additional product candidates we identify and develop or expand development of existing programs into additional patient populations;
- maintain, expand, enforce, defend and protect our intellectual property portfolio and provide reimbursement of third-party expenses
 related to our patent portfolio;
- seek regulatory and marketing approvals for any of our product candidates that we develop;
- perform research services under the Vertex Agreement and seek to identify, establish and maintain additional collaborations and license agreements, and the success of those collaborations and license agreements;
- make milestone payments to Beam under our amended and restated collaboration and license agreement with Beam, milestone
 payments to Acuitas under our non-exclusive license agreement with Acuitas, milestone payments or success payments to Harvard and
 Broad under the Harvard/ Broad License Agreements, and milestone payments to Novartis under our license agreement with Novartis,
 and potential payments to other third parties under our other collaboration agreements or under any additional future collaboration or
 license agreements that we obtain;
- ultimately establish a sales, marketing, and distribution infrastructure to commercialize any drug products for which we may obtain marketing approval, either by ourselves or in collaboration with others;
- generate revenue from commercial sales of product candidates we may develop for which we receive marketing approval;
- further develop base editing and novel gene editing technology;
- hire additional personnel including research and development, clinical and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development;
- · acquire or in-license products, intellectual property, medicines and technologies;
- satisfy any post-marketing requirements, such as a cardiovascular outcomes trial;
- · establish commercial-scale current good manufacturing practices capabilities through a third-party or our own manufacturing facility; and
- continue to operate as a public company.

As of September 30, 2022, we had cash, cash equivalents and marketable securities of \$550.7 million. We believe that our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2025. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Our expectation with respect to our ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to management and there can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, and we may need to seek additional funds sooner than planned.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not have any source of committed external funds. Market volatility could also adversely impact our ability to access capital as and when needed. Additional capital raised through the sale of equity or convertible debt securities may include liquidation or other preferences. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures or declaring dividends and may require the issuance of warrants.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we

may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations

During the three months ended September 30, 2022, there were no material changes to our contractual obligations and commitments from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual obligations" in our Annual Report on Form 10-K filed with the SEC on March 14, 2022. Refer to Note 7, "Leases," to the condensed consolidated financial statements appearing in Part I, Item 1 in this Quarterly Report on Form 10-Q for more information on our lease obligations.

Emerging growth company status

As an emerging growth company, or EGC, under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited financial statements in a registration statement for an IPO, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an EGC to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We may remain classified as an EGC until December 31, 2026, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30 before that time or if we have annual gross revenues of \$1.07 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than \$1 billion of non-convertible debt over a three-year period.

Critical accounting policies and significant judgments

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements and related disclosures requires us to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Except for the addition of Revenue Recognition, during the three and nine months ended September 30, 2022, there were no material changes to our critical accounting policies from those described in our Annual Report on Form 10-K filed with the SEC on March 14, 2022.

Revenue Recognition

We enter into collaboration agreements which are within the scope of ASC Topic 606, "Revenue from Contracts with Customers" ("ASC 606"), under which we license rights to certain of our product candidates and perform research and development services. The terms of these arrangements typically include payment of one or more of the following: non-refundable, upfront fees; reimbursement of research and development costs; development, regulatory, and commercial milestone payments; and royalties on net sales of licensed products.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To

determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The promised goods or services in our arrangements typically consist of license rights to our intellectual property and research and development services. We provide options to additional items in the contracts, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. We evaluate the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available and whether the goods or services are integral or dependent to other goods or services in the contract.

We estimate the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each arrangement that includes variable consideration, we evaluate the number of potential payments and the likelihood that the payments will be received. We utilize either the most likely amount method or expected amount method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration which is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

Our contracts often include development and regulatory milestone payments which are assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues in the period of adjustment. To date, we have not recognized any consideration related to the achievement of development, regulatory, or commercial milestone revenue resulting from any of our collaboration arrangements.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any consideration related to sales-based royalty revenue resulting from any of our collaboration arrangements.

We allocate the transaction price based on the estimated stand-alone selling price of each of the performance obligations. We must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the stand-alone selling price for service obligations, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Additionally, in determining the standalone selling price for material rights, we utilize comparable transactions, clinical trial success probabilities, and estimates of option exercise likelihood. Variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts we would expect to receive for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. We evaluate

the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Upfront payments and fees are recorded as deferred revenue upon receipt or when due until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional.

Recently issued accounting pronouncements

See Note 2, "Summary of significant accounting policies – Recently issued accounting pronouncements" to our consolidated financial statements included in our Annual Report on Form 10-K filed with the SEC on March 14, 2022.

Item 3. Quantitative and qualitative disclosures about market risk

Interest rate risk

We are exposed to market risk related to changes in interest rates. As of September 30, 2022, we had cash and cash equivalents of \$277.0 million, which consisted of standard checking accounts and money market account funds that invest primarily in U.S. government-backed securities and treasuries. In addition, as of September 30, 2022, we also had marketable securities of \$273.7 million, which consist of U.S. treasury securities and agency securities. Interest income is sensitive to change in the general level of interest rates, however, due to the short-term maturities of our cash equivalents and the low risk profile of our marketable securities, an immediate 10% change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities.

Foreign currency exchange risk

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we do contract with vendors that are located outside of the United States and may be subject to fluctuations in foreign currency rates. We may enter into additional contracts with vendors located outside of the United States in the future, which may increase our foreign currency exchange risk.

Inflation generally affects us by increasing our cost of labor and target development costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three and nine months ended September 30, 2022.

Item 4. Controls and procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2022, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II — Other Information

Item 1. Legal proceedings

We are currently not a party to any material legal proceedings.

Item 1A. Risk factors

Our future operating results could differ materially from the results described in this Quarterly Report on Form 10-Q due to the risks and uncertainties described below. You should consider carefully the following information about risks below in evaluating our business. If any of the following risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See page i of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. Factors that could cause or contribute to such differences include those factors discussed below.

Risks related to our financial position and need for additional capital

We have incurred significant losses since our inception and have no products approved for sale. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception, we have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials, and have incurred significant operating losses. Our net losses were \$116.3 million for the nine months ended September 30, 2022 and \$120.3 million for the year ended December 31, 2021. As of September 30, 2022, we had an accumulated deficit of \$303.2 million. Prior to the execution of the Strategic Collaboration and License Agreement, or the Vertex Agreement, with Vertex Pharmaceuticals Incorporated, or Vertex, in July 2022 we had generated no revenue. We have financed our operations primarily through private placements of our preferred stock and common stock and from the sale of common stock in public offerings and payments received in connection with the Vertex Agreement. We have devoted all of our efforts to research and development and are still in the early stages of development of our research programs. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our operating expenses and net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- conduct our ongoing heart-1 clinical trial for VERVE-101 in New Zealand and the United Kingdom, and if our investigational new drug
 application, or IND, is cleared, in the United States;
- continue our current research programs and our preclinical development of product candidates from our current research programs;
- seek to identify additional research programs and additional product candidates;
- advance our existing and future product candidates into clinical development;
- initiate preclinical studies and clinical trials for any additional product candidates we identify and develop or expand development of
 existing programs into additional patient populations;
- maintain, expand, enforce, defend and protect our intellectual property portfolio and provide reimbursement of third-party expenses
 related to our patent portfolio;
- · seek regulatory and marketing approvals for any of our product candidates that we develop;
- perform research services under the Vertex Agreement and seek to identify, establish and maintain additional collaborations and license agreements, and the success of those collaborations and license agreements;
- make milestone payments to Beam Therapeutics Inc., or Beam, under our amended and restated collaboration and license agreement with Beam, or the Beam Agreement, milestone payments to Acuitas Therapeutics Inc., or Acuitas, under our non-exclusive license agreement with Acuitas, or the Acuitas Agreement, milestone payments or success payments to The Broad Institute, Inc., or Broad, and the President and Fellows of Harvard College, or Harvard, under our license agreement with Broad and Harvard (as amended, the Cas9 License Agreement), and milestone payments to Novartis Pharma AG, or Novartis, under our license agreement with Novartis, or the Novartis Agreement, and

potential payments to other third parties under our other collaboration agreements or any additional future collaboration or license agreements that we obtain;

- ultimately establish a sales, marketing, and distribution infrastructure to commercialize any drug products for which we may obtain
 marketing approval, either by ourselves or in collaboration with others;
- generate revenue from commercial sales of product candidates we may develop for which we receive marketing approval;
- further develop base editing and novel gene editing technology:
- · hire additional personnel including research and development, clinical and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development;
- acquire or in-license products, intellectual property, medicines and technologies;
- satisfy any post-marketing requirements, such as a cardiovascular outcomes trial, or CVOT;
- establish commercial-scale current good manufacturing practices capabilities, or cGMP, through a third-party or our own manufacturing facility; and
- continue to operate as a public company.

In addition, our expenses will increase if, among other things:

- we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other regulatory
 authorities to perform trials or studies in addition to, or different than, those expected;
- · there are any delays in completing our clinical trials or the development of any of our product candidates; or
- there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Even if we obtain marketing approval for, and are successful in commercializing, one or more of our product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional product candidates and/or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

We have never generated revenue from product sales and may never achieve or maintain profitability.

We have only recently initiated clinical development of our first product candidate and expect that it will be many years, if ever, before we have a product candidate ready for commercialization. To become and remain profitable, we must succeed in developing, obtaining the necessary regulatory approvals for and eventually commercializing a product or products that generate significant revenue. The ability to achieve this success will require us to be effective in a range of challenging activities, including:

- · completing preclinical testing and clinical trials;
- identifying additional product candidates;
- obtaining marketing approval for these product candidates;
- manufacturing, marketing and selling any products for which we may obtain marketing approval; and
- achieving market acceptance of products for which we may obtain marketing approval as viable treatment options.

We are only in the preliminary stages of these activities and there is no assurance that we will be successful in these activities and, even if we are, may never generate revenues that are significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate revenue or achieve profitability.

Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our

addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct our ongoing Phase 1 clinical trial of VERVE-101, continue research, development and preclinical testing, initiate additional clinical trials and potentially seek marketing approval for VERVE-101, VERVE-201, and any other product candidates we may develop. We expect our expenses to increase substantially in connection with our ongoing and planned activities, particularly as we advance our preclinical activities and our ongoing and planned clinical trials. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. We currently do not have a credit facility or any committed sources of capital. If we are unable to raise capital or obtain adequate funds when needed or on acceptable terms, we may be forced to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our future capital requirements will depend on many factors, including:

- the costs of developing or acquiring licenses for the delivery modalities that will be used with our future product candidates;
- the progress, costs and results of our ongoing Phase 1 clinical trial of VERVE-101 and any future clinical development of VERVE-101;
- the scope, progress, results and costs of discovery, preclinical and clinical development for any product candidates we may develop;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and
 proprietary rights, and defending intellectual property-related claims, including claims of infringement, misappropriation or other violation
 of third-party intellectual property;
- the costs, timing and outcome of regulatory review of the product candidates we may develop;
- the costs of future commercialization activities, either by ourselves or in collaboration with others, including product sales, marketing, manufacturing, and distribution for any product candidates for which we receive marketing approval;
- the costs of satisfying any post-marketing requirements, such as a CVOT;
- the revenue, if any, received from commercial sales of product candidates we may develop for which we receive marketing approval;
- the success of our license agreements and our collaborations;
- · our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we obtain;
- the extent to which we acquire or in-license products, intellectual property and technologies;
- · the costs of operational, financial and management information systems and associated personnel; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, even if we successfully identify and develop product candidates and those are approved, we may not achieve commercial success. Our commercial revenues, if any, may not be sufficient to sustain our operations. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

As of September 30, 2022, we had cash, cash equivalents and marketable securities of approximately \$550.7 million. We believe that our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2025. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. As a result, we could deplete our capital resources sooner than we currently expect and could be forced to seek additional funding sooner than planned.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize any product candidates. We cannot be certain that additional funding will be available on acceptable terms, or at all. For example, while the potential impact and duration of the COVID-19 pandemic on the global economy and our business in particular may be difficult to assess or predict, the pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, which could in the future negatively affect our liquidity. We have no committed source of additional capital and, if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. We could be required to seek collaborators for product candidates we may develop at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to product candidates we may develop in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenues from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not have any source of committed external funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as a common stockholder. Any debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our limited operating history may make it difficult for stockholders to evaluate the success of our business to date and to assess our future viability.

We commenced operations in 2018 and are a clinical-stage company. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates, securing intellectual property rights, conducting preclinical studies and an early-stage clinical trial. We initiated our first clinical trial, a Phase 1 clinical trial for VERVE-101, in July 2022. Our other research programs, including VERVE-201, are still in the research or preclinical stage of development, and their risk of failure is high. We have not yet demonstrated our ability to complete any clinical trials, obtain marketing approvals, manufacture a clinical development or commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. In part because of this lack of experience, we cannot be certain that our ongoing preclinical studies and clinical trial will be completed on time or if the planned preclinical studies and clinical trials will begin or be completed on time, if at all. Consequently, any predictions stockholders make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing gene editing products.

Our limited operating history, particularly in light of the rapidly evolving genetic medicines field, may make it difficult to evaluate our technology and industry and predict our future performance. Our limited history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and

difficulties frequently experienced by early-stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

In addition, as our business grows, we may encounter unforeseen expenses, restrictions, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Our ability to use our net operating losses and research and development tax credit carryforwards to offset future taxable income or taxes may be subject to certain limitations.

We have a history of cumulative losses and anticipate that we will continue to incur significant losses in the foreseeable future; thus, we do not know whether or when we will generate taxable income necessary to utilize our net operating losses, or NOLs, or research and development tax credit carryforwards. As of December 31, 2021, we had federal NOL carryforwards of \$124.7 million and state NOL carryforwards of \$114.4 million.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and research and development tax credit carryforwards to offset post-change taxable income or taxes. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced such ownership changes in the past and may experience such ownership changes in the future as a result of subsequent changes in our stock ownership (which may be outside our control). As a result, if, and to the extent that, we earn net taxable income, our ability to use our pre-change NOLs and research and development tax credit carryforwards to offset such taxable income may be subject to limitations. Our NOLs or credits may also be impaired under state law.

There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. As described below in "Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition," the Tax Cuts and Jobs Act, or the Tax Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, included changes to U.S. federal tax rates and the rules governing NOL carryforwards that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

Risks related to discovery and development

We are very early in our development efforts, and we have not yet completed a clinical trial of any product candidate. As a result, we expect it will be many years before we commercialize any product candidate, if ever. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts and have focused our research and development efforts to date primarily on research efforts and preclinical development. We initiated our first clinical trial, a Phase 1 clinical trial for VERVE-101 in July 2022, but we have not yet completed a clinical trial of any product candidate. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development, marketing approval and eventual commercialization of our product candidates, which may never occur. We have not yet generated revenue from product sales, and we may never be able to develop or commercialize a marketable product.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND and finalizing the trial design based on discussions with the FDA and other regulatory authorities.

The FDA or other regulatory agencies may require us to complete additional preclinical studies or require us to satisfy other requests prior to commencing clinical trials in the respective countries, which may delay our clinical trials beyond our planned timeline. For example, in November 2022, the FDA placed the IND application to conduct a clinical trial evaluating VERVE-101 in the United States on hold. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial, including with respect to VERVE-101, or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials, delay the enrollment of our clinical trials or impose stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to CTAs in other countries, including countries in the European Union.

Commercialization of any product candidates we may develop will require preclinical and clinical development; regulatory and marketing approval in multiple jurisdictions, including by the FDA and the EMA; manufacturing supply, capacity and expertise; a commercial organization; and significant marketing efforts. The success of VERVE-101, VERVE-201 and any other product candidates we may identify and develop will depend on many factors, including the following:

- timely and successful completion of preclinical studies, including toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, where applicable;
- effective INDs or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for any product candidates we may develop;
- successful enrollment and completion of clinical trials, including under the FDA's current Good Clinical Practices, or GCPs, current Good Laboratory Practices and any additional regulatory requirements from foreign regulatory authorities;
- positive results from our ongoing and future clinical trials that support a finding of safety and effectiveness and an acceptable risk-benefit profile in the intended populations;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment of arrangements through our own facilities or with third-party manufacturers for clinical supply and, where applicable, commercial manufacturing capabilities;
- establishment, maintenance, defense and enforcement of patent, trademark, trade secret and other intellectual property protection or regulatory exclusivity for any product candidates we may develop;
- · commercial launch of any product candidates we may develop, if approved, whether alone or in collaboration with others;
- acceptance of the benefits and use of our product candidates we may develop, including method of administration, if and when approved, by patients, the medical community and third-party payers;
- · effective competition with other therapies;
- maintenance of a continued acceptable safety, tolerability and efficacy profile of any product candidates we may develop following approval; and
- establishment and maintenance of healthcare coverage and adequate reimbursement by payers.

If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any product candidates we may develop, which would materially harm our business. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

Gene editing, including base editing, is a novel technology that is not yet clinically validated as being safe and efficacious for human therapeutic use. The approaches we are taking to discover and develop novel therapeutics are unproven and may never lead to marketable products.

We are focused on developing medicines utilizing gene editing technology, which is new and largely unproven. The base editing technologies that we have licensed and that we are utilizing with VERVE-101 and VERVE-201 have not yet been evaluated in any completed clinical trial, nor are we aware of any clinical trials for safety or efficacy having been completed by third parties using our base editing or similar technologies. The scientific evidence to support the feasibility of developing product candidates based on gene editing technologies is both preliminary and limited. Successful development of our product candidates will require us to safely deliver a gene editor into target cells, optimize the efficiency and specificity of such product candidates and ensure the therapeutic selectivity of such product candidates. There can be no assurance that base editing technology, or other gene editing technology, will lead to the development of genetic medicines or that we will be successful in solving any or all of these issues.

Our future success is highly dependent on the successful development of gene editing technologies, delivery technology methods and therapeutic applications of that technology. We may decide to alter or abandon our initial programs as new data become available and we gain experience in developing gene editing therapeutics. We cannot be sure that our technologies will yield satisfactory products that are safe and effective, scalable or profitable in our initial indications or any other indication we pursue. Adverse developments in the clinical development efforts of other gene editing technology companies could adversely affect our efforts or the perception of our product candidates by both investors and regulatory authorities.

Similarly, another new gene editing technology that has not been discovered yet may be developed by third parties and may be determined to be more attractive than base editing for the gene targets that we are pursuing with base editing technology. We also are seeking to develop a novel gene editing development candidate as part of our collaboration with Vertex, including seeking to identify and engineer specific gene editing systems and delivery systems directed to a target of interest. We have not previously developed novel gene editing technology on our own and have in-licensed gene editing technology from third parties. We cannot be certain that we will be able to successfully develop novel gene editing systems for the target or for any other targets.

Moreover, we cannot be certain we will be able to obtain any necessary rights to develop other gene editing technologies. Although all of our founders who currently provide consulting and advisory services to us in the area of base editing technologies have assignment of inventions obligations to us with respect to the services they perform for us, these assignment of inventions obligations are subject to limitations and do not extend to their work in other fields or to the intellectual property arising from their employment with their respective academic and research institutions. To obtain intellectual property rights assigned by these founders to such institutions, we would need to enter into license agreements with such institutions, which may not be available on commercially reasonable terms or at all. Any of these factors could reduce or eliminate our commercial opportunity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Development activities in the field of gene editing are currently subject to a number of risks related to the ownership and use of certain intellectual property rights that are subject to patent interference proceedings in the United States and opposition proceedings in Europe. For additional information regarding the risks that may apply to our and our licensors' intellectual property rights, see the section entitled "—Risks related to our intellectual property" for more information.

Additionally, public perception and related media coverage relating to the adoption of new therapeutics or novel approaches to treatment, as well as ethical concerns related specifically to gene editing, may adversely influence the willingness of subjects to participate in clinical trials, or, if any therapeutic is approved, of physicians and patients to accept these novel and personalized treatments. Physicians, health care providers and third-party payors often are slow to adopt new products, technologies and treatment practices, particularly those that may also require additional upfront costs and training. Physicians may not be willing to undergo training to adopt these novel and potentially personalized therapies, may decide the particular therapy is too complex or potentially risky to adopt without appropriate training, and may choose not to administer the therapy. Further, due to health conditions, genetic profile or other reasons, certain patients may not be candidates for the therapies. In addition, responses by federal and state agencies, Congressional committees and foreign governments to negative public perception, ethical concerns or financial considerations may result in new legislation, regulations or medical standards that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. New government requirements may be established that could delay or prevent regulatory approval of our product candidates under development. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be. Based on these and other factors, health care providers and payors may decide that the benefits of these new therapies do not or will not outweigh their costs.

The gene editing field is relatively new and is evolving rapidly. We are focusing our research and development efforts on gene editing using base editing technology, but other gene editing technologies may be discovered that provide significant advantages over base editing, which could materially harm our business.

To date, we have focused our efforts on gene editing technologies using base editing. Other companies have previously undertaken research and development of gene editing technologies using zinc finger nucleases, engineered meganucleases and transcription activator-like effector nucleases, but to date none have obtained marketing approval for a product candidate. There can be no certainty that base editing technology will lead to the development of genetic medicines or that other gene editing technologies will not be considered better or more attractive for the development of medicines. For example, Feng Zhang's group at the Massachusetts Institute of Technology, or MIT, and Broad, and, separately, Samuel Sternberg's group at Columbia University recently announced the discovery of the use of transposons, or "jumping genes." Transposons can insert themselves into different places in the genome and can be programmed to carry specific DNA sequences to specific sites, without the need for making double-stranded breaks in DNA. Beam uses prime editing technology, which utilizes a CRISPR protein to target a mutation site in DNA and to nick a single strand of the target DNA. Guide RNA allows the CRISPR protein to recognize a DNA sequence that is complementary to the guide RNA and also carries a primer for reverse transcription and a replacement template. The reverse transcriptase copies the template sequence in the nicked site, installing the edit.

A number of alternative approaches are being developed by others, including, for example, Intellia Therapeutics, Inc., which recently reported clinical data from a Phase 1 trial of NTLA-2001, a CRISPR/Cas9-based gene editing product candidate for the treatment of hereditary transthyretin amyloidosis with polyneuropathy. Similarly, other new gene editing

technologies that have not been discovered yet may be more attractive than base editing. Moreover, we cannot be certain we will be able to obtain rights to develop or use other gene editing technologies. Any of these factors could reduce or eliminate our commercial opportunity, and could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be successful in our efforts to identify and develop potential product candidates. If these efforts are unsuccessful, we may never become a commercial stage company or generate any revenues.

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates using gene editing technologies. We have only recently initiated our first clinical trial of VERVE-101 in New Zealand and the United Kingdom. Our research programs may fail to identify potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying additional potential product candidates, our potential product candidates may be shown to have harmful side effects in preclinical *in vitro* experiments or animal model studies, they may not show promising signals of therapeutic effect in such experiments or studies or they may have other characteristics that may make the product candidates impractical to manufacture, unmarketable or unlikely to receive marketing approval.

The COVID-19 pandemic may affect our ability to initiate and complete current or future preclinical studies and clinical trials, disrupt regulatory activities or have other adverse effects on our business and operations. In addition, this pandemic has adversely impacted economies worldwide, which could result in adverse effects on our business, operations and prospects.

The COVID-19 pandemic has caused, and may continue to cause, many governments to implement measures to slow the spread of the pandemic through quarantines, travel restrictions, heightened border scrutiny and other measures. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen.

The future progression of the pandemic and its effects on our business and operations are uncertain. We and our contract manufacturing organizations, or CMOs, and contract research organizations, or CROs, have experienced a reduction in the capacity to undertake research-scale production and to execute some preclinical studies, and we have faced and may face disruptions that affect our ability to initiate and complete preclinical studies and clinical trials, and disruptions in procuring items that are essential for our research and development activities, including:

- raw materials and supplies used in the production and purification of messenger RNA, or mRNA, nucleic acids as well as lipids used in the production of lipid nanoparticles, or LNPs;
- · raw materials and supplies used in the manufacture of any product candidates we may develop;
- · laboratory supplies used in our preclinical studies and clinical trials; and
- animals that are used for preclinical testing for which there are shortages because of ongoing efforts to address components of the pandemic.

We and our CROs and CMOs may also face disruptions related to our ongoing and future IND-enabling studies and clinical trials arising from delays in preclinical studies, manufacturing disruptions, and the ability to obtain necessary institutional review board, or IRB, institutional biosafety committee, or IBC, or other necessary site approvals, as well as other delays at clinical trial sites.

The response to the COVID-19 pandemic may also redirect resources with respect to regulatory and intellectual property matters in a way that would adversely impact our ability to progress regulatory approvals and protect our intellectual property, for example by causing interruptions or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines. We have experienced delays with the FDA as a result of the COVID-19 pandemic. In addition, we may face impediments or delays to regulatory meetings and approvals due to measures intended to limit in-person interactions. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business, although for the reasons described above it has the potential to adversely affect our business, financial condition, results of operations and prospects.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The risk of failure for each of our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. The time required to obtain approval from the FDA, EMA or other comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We have only recently initiated a clinical trial for VERVE-101 in New Zealand and the United Kingdom and have not yet completed any clinical trials. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. Even if initial clinical trials in any of our product candidates we may develop are successful, these product candidates we may develop may fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through preclinical studies and initial clinical trials. There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage clinical trials. Furthermore, even if the clinical trials are successful, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs and other regulatory filings in the United States and abroad. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the outcome of our preclinical testing and studies will ultimately support the further development of our current or future product candidates or whether regulatory authorities will accept our proposed clinical programs. As a result, we may not be able to submit an IND in the United States or comparable foreign applications to initiate clinical development on the timelines we expect, if at all, and the submission of these applications may not result in regulatory authorities allowing clinical trials to begin.

For example, in November 2022, the FDA placed our IND application to conduct a clinical trial evaluating VERVE-101 in the United States on hold. Prior to initiating the trial in the United States, we will be required to resolve the hold on the IND application. We cannot be certain that the hold will be lifted on a timely basis, or at all, and we may not be able to initiate our clinical trial of VERVE-101 in the United States. Any delay in our ability, or our inability, to initiate our clinical trial of VERVE-101 in the United States because of the hold may delay our clinical development plans for VERVE-101, may require us to incur additional clinical development costs and could impair our ability to ultimately obtain FDA approval for VERVE-101. Delays in the completion of any clinical trial of VERVE-101 could increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue.

Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. We cannot guarantee that any of our clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, but not limited to, flaws in study design, dose selection issues, placebo effects, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits.

Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Furthermore, the failure of any of our product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates and/or cause the FDA, EMA or other regulatory authorities to require additional testing before approving any of our product candidates.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or other foreign regulatory authorities that a product candidate is safe, pure and potent or effective for its proposed indication;

- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or other foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA or other foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application, or BLA, to the FDA, or similar foreign submission to the EMA or other foreign regulatory authority, to obtain approval in the United States, the European Union or elsewhere;
- the FDA, EMA or other foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or other foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, financial condition, results of operations and prospects.

The FDA, EMA and other comparable foreign regulatory authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any product candidate that we develop. Even if we believe the data collected from our ongoing or future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA or any other comparable foreign regulatory authorities.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Additionally, outside of the United States, regulatory authorities may not approve the price we intend to charge for our products. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

In response to the COVID-19 pandemic, the FDA issued guidance on March 18, 2020, and subsequently updated it on July 2, 2020, January 27, 2021, and August 30, 2021, to address the conduct of clinical trials during the pandemic. The guidance sets out a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical study report (or as a separate document) contingency measures implemented to manage the study, and any disruption of the study as a result of COVID-19; a list of all study participants affected by COVID-19-related study disruptions by a unique subject identifier and by investigational site, and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the study. In its most recent update to this guidance, FDA addresses questions received during the past year from clinical practitioners who are adapting their operations in a pandemic environment. These questions focused on, among other things, when to suspend, continue or initiate a trial and how to submit changes to protocols for INDs and handle remote site monitoring visits. There is no assurance that this guidance governing clinical studies during the pandemic will remain in effect or, even if it does, that it will help address the risks and challenges enumerated above. Accordingly, our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain additional financing if needed.

Accordingly, the COVID-19 pandemic may continue to significantly impact economies and financial markets worldwide, which could result in adverse effects on our business and operations, impact our ability to raise additional funds through public offerings and impact the volatility of our stock price and trading in our stock. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and it has the potential to adversely affect our business, financial condition, results of operations, and prospects.

The outcome of preclinical studies and earlier-stage clinical trials may not be predictive of future results or the success of later preclinical studies and clinical trials.

We have only recently initiated and begun conducting a clinical trial. As a result, our belief in the potential capabilities of our programs is based on early research and preclinical studies. However, the results of preclinical studies may not be predictive of the results of later preclinical studies or clinical trials, and the results of any early-stage clinical trials may not be predictive of the results of later clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. We have conducted several preclinical studies of our product candidates in non-human primates, but we cannot be certain that the results observed in such studies will translate into similar results in clinical trials of our product candidates in humans. Our ongoing or future clinical trials may not ultimately be successful or support further clinical development of any product candidates we may develop. There is a high failure rate for product candidates proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving encouraging results in earlier studies. Any such setbacks in our clinical development could materially harm our business and results of operations.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators, IRBs or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- regulators may decide that longer follow-up data are needed before they will consider our marketing application, which would delay our ability to obtain approval;
- regulators may decide the design of our clinical trials is flawed, for example if regulators do not agree with our chosen primary endpoints;
- regulators may decide to slow patient enrollment, resulting in delays to our ability to meet our timelines;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- preclinical testing may produce results based on which we may decide, or regulators may require us, to conduct additional preclinical studies before we proceed with certain clinical trials, limit the scope of our clinical trials, halt ongoing clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, IRBs or ethics committees may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain regulatory approval, such as a CVOT;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- · the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the trials; and

 regulators may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a risk evaluation and mitigation strategy, or REMS.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are conducted or their ethics committees, by the data review committee or data safety monitoring board for such trial or by the FDA, EMA or other foreign regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including those relating to the class of products to which our product candidates belong.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- · be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling or a REMS that includes significant use or distribution restrictions or safety warnings;
- · be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our development costs will also increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also determine to change the design or protocol of one or more of our clinical trials, including to add additional patients or arms, which could result in increased costs and expenses and/or delays. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Preclinical drug development is uncertain. Some or all of our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain marketing approvals or commercialize these product candidates on a timely basis or at all, which would have an adverse effect on our business.

In order to obtain FDA approval to market a new biological product, we must demonstrate product purity (or product quality) as well as proof of safety and potency or efficacy in humans. To satisfy these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support an IND in the United States. We cannot be certain of the timely completion or outcome of our preclinical testing and studies, and we cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of these product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for any preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. For example, in November 2022, the FDA placed the IND application to conduct a clinical trial evaluating VERVE-101 in the United States on hold.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per product candidate. Delays associated with product candidates for which we are conducting preclinical testing and studies ourselves may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the preclinical testing and studies of certain product candidates conducted by our potential partners over which we have no control. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- · inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical trials; and
- · delays in reaching a consensus with regulatory agencies on study design.

Moreover, even if we do initiate clinical trials for other product candidates, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate product purity (or quality) as well as proof of safety and potency or efficacy necessary to obtain the requisite marketing approvals for any of our product candidates or product candidates employing our technology. Even if we obtain positive results from preclinical studies or initial clinical trials, we may not achieve the same success in future trials.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

Identifying and qualifying patients to participate in clinical trials for our product candidates is critical to our success. We recently initiated our heart-1 clinical trial for VERVE-101 in New Zealand and the United Kingdom under country-specific protocols with various modifications to eligibility in each country. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in the trial until its conclusion. We may not be able to initiate or continue additional clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside of the United States. Given the large patient population for atherosclerotic cardiovascular disease, or ASCVD, if we expand clinical development of VERVE-101 for the treatment of patients with established ASCVD, the number of patients that may be required for clinical trials could be high, we may not be able to enroll a sufficient number of patients and we may not be able to initiate or complete clinical trials of VERVE-101 for the treatment of patients with established ASCVD. Because of the small patient population for homozygous familial hypercholesterolemia, or HoFH, we may have difficulty enrolling patients and we may not be able to initiate or complete clinical trials for our ANGPTL3 program for the treatment of HoFH.

Patient enrollment is affected by a variety of other factors, including:

- the prevalence and severity of the disease under investigation;
- · the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate under trial;
- the requirements of the trial protocols, which for products targeting cardiovascular disease, or CVD, could include up to 15 years of longterm patient follow-up;
- the availability of existing treatments for the indications for which we are conducting clinical trials;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- · the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients;
- · perceived negative public perception of gene editing;
- the conduct of clinical trials by competitors for product candidates that treat the same indications or address the same patient populations as our product candidates; and
- the cost to, or lack of adequate compensation for, prospective patients.

Other pharmaceutical and biotechnology companies have reported experiencing delays in enrollment in their ongoing clinical trials as a result of the COVID-19 pandemic, and we could also experience such delays. Our inability to locate and enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Even if we are able to enroll a sufficient number of patients for our future clinical trials, we may have difficulty maintaining patients in our clinical trials. Many of the patients who end up receiving placebo may perceive that they are not receiving the product candidate being tested, and they may decide to withdraw from our clinical trials to pursue alternative therapies rather than continue the trial. If we have difficulty enrolling or maintaining a sufficient number of patients to conduct our clinical trials, we may need to delay, limit or terminate clinical trials, any of which would harm our business, financial condition, results of operations and prospects.

If any of the product candidates we may develop, or the delivery modes we rely on to administer them, cause serious adverse events, undesirable side effects or unexpected characteristics, such events, side effects or characteristics could delay or prevent regulatory approval of the product candidates, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

We only recently initiated our heart-1 clinical trial for VERVE-101. Moreover, there have been only a limited number of clinical trials involving the use of gene editing technologies and none involving base editing technology similar to our technology. Furthermore, there has not been any gene editing product candidate that has received regulatory approval for use in humans. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. There can be no assurance that gene editing technologies will not cause undesirable side effects, as improper editing of a patient's DNA could lead to lymphoma, leukemia or other cancers or other aberrantly functioning cells.

A significant risk in any gene editing product candidate is that "off-target" edits may occur, which could cause serious adverse events, undesirable side effects or unexpected characteristics. We cannot be certain that off-target editing will not occur in any of our ongoing or future clinical studies, and the lack of observed side effects in preclinical studies does not guarantee that such side effects will not occur in human clinical studies. There is also the potential risk of delayed or late presentation of adverse events following exposure to gene editors due to the potential permanence of edits to DNA or due to other components of product candidates used to carry the genetic material. Further, because gene editing makes a permanent change, the therapy cannot be withdrawn, even after a side effect is observed.

We are using LNPs to deliver our gene editors to the liver. LNPs have recently been used to deliver mRNA in humans, including the COVID-19 vaccines developed by Pfizer Inc., or Pfizer, and BioNTech SE and by Moderna, Inc., and LNPs are being used to deliver mRNA for therapeutic use in clinical trials. LNPs have the potential to induce liver injury and/or initiate a systemic inflammatory response, either of which could potentially be fatal. While we aim to continue to optimize our LNPs, there can be no assurance that our LNPs will not have undesired effects. Our LNPs could contribute, in whole or in part, to one or more of the following: liver injury, immune reactions, infusion reactions, complement reactions, opsonization reactions, antibody reactions including IgA, IgM, IgE or IgG or some combination thereof, or reactions to the polyethylene glycol, or PEG, from some lipids or PEG otherwise associated with the LNP. Certain aspects of our investigational medicines may induce immune reactions from either the mRNA or the lipid as well as adverse reactions within liver pathways or degradation of the mRNA or the LNP, any of which could lead to significant adverse events in one or more of our ongoing or future clinical trials. Some of these types of adverse effects have been observed for other LNPs. There may be uncertainty as to the underlying cause of any such adverse event, which would make it difficult to accurately predict side effects in ongoing or future clinical trials and would result in significant delays in our programs.

Our GalNAc-LNPs, which we plan to use in VERVE-201, are a novel delivery mechanism for delivery of gene editors to the liver and have not yet been studied in humans.

If any product candidates we develop are associated with serious adverse events, undesirable side effects or unexpected characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects.

If in the future we are unable to demonstrate that any of the above adverse events were caused by factors other than our product candidate, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates we are able to develop for any or all targeted indications. They could also revoke a marketing authorization if a serious safety concern is identified in any post-marketing follow up studies. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any product candidate we may develop, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to identify and develop product candidates, and may harm our business, financial condition, result of operations, and prospects significantly.

Adverse public perception of genetic medicines, and gene editing and base editing in particular, may negatively impact regulatory approval of, and/or demand for, our potential products.

Our programs involve editing the human genome. The clinical and commercial success of our product candidates will depend in part on public understanding and acceptance of the use of gene editing therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene editing is unsafe, unethical or immoral, and, consequently, our product candidates may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we

may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

In addition, gene editing technology is subject to public debate and heightened regulatory scrutiny due to ethical concerns.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair our development and commercialization of product candidates or demand for any product candidates we may develop. Adverse events in our preclinical studies or clinical trials or those of our licensors, partners or competitors or of academic researchers utilizing gene editing technologies, even if not ultimately attributable to product candidates we may identify and develop, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential product candidates we may identify and develop, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. Use of gene editing technology by a third party or government to develop biological agents or products that threaten U.S. national security could similarly result in such negative impacts to us.

Interim and preliminary results from our clinical trials that we announce or publish from time to time may change as more participant data become available and are subject to audit and verification procedures, which could result in material changes in the final data.

From time to time, we may publish or report interim or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available. For example, our clinical trial design for our Phase 1 clinical trial of VERVE-101 includes an interim analysis of three-month data from dose-escalation part of the trial and these data could be materially different than the data reported at the end of the trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. Preliminary, interim or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or interim data we previously published. As a result, preliminary, interim or top-line data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could be material and could significantly harm our reputation and business prospects and may cause the trading price of our common stock to fluctuate significantly.

Genetic medicines are complex and difficult to manufacture. We could experience delays in satisfying regulatory authorities or production problems that result in delays in our development programs, limit the supply of our product candidates we may develop, or otherwise harm our business.

Any product candidates we may develop will likely require processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as the product candidates we intend to develop generally cannot be fully characterized. As a result, assays of the finished product candidate may not be sufficient to ensure that the product candidate will perform in the intended manner. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory or potentially delay progression of our potential IND filings. If we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. In addition, the product candidates we may develop will require complicated delivery modalities, such as LNPs, which will introduce additional complexities in the manufacturing process.

In addition, the FDA, the EMA and other regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to manage our manufacturing process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements.

Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and cause reputational damage. Some of the raw materials that we anticipate will be required in our manufacturing process

are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of any product candidates we may develop could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially harm our development timelines and our business, financial condition, results of operations and prospects.

Any problems in our manufacturing process or the facilities with which we contract could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs. Problems in third-party manufacturing process or facilities also could restrict our ability to ensure sufficient clinical material for any clinical trials we may be conducting or are planning to conduct and meet market demand for any product candidates we develop and commercialize.

If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives regulatory approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal or limitation by regulatory authorities of approvals of such product;
- · seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a "black box" warning or contraindication;
- requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and
- · harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Failure to allocate resources or capitalize on strategies in a successful manner will have an adverse impact on our business, financial condition and results of operations.

We are conducting a clinical trial, and plan to conduct additional clinical trials, at sites outside the United States. The FDA may not accept data from trials conducted in such locations, and the conduct of trials outside the United States could subject us to additional delays and expense.

We are conducting and plan to conduct one or more of additional clinical trials with one or more trial sites that are located outside the United States, including our ongoing Phase 1 trial of VERVE-101 at trial sites in New Zealand and the United Kingdom. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with ethical principles. The FDA must be able to validate the data from the trial through an onsite inspection, if necessary. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, whether the FDA accepts the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates.

In addition, conducting clinical trials outside the United States could have a significant adverse impact on us. Risks inherent in conducting international clinical trials include:

- · clinical practice patterns and standards of care that vary widely among countries;
- non-U.S. regulatory authority requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schema;
- · foreign exchange fluctuations; and
- diminished protection of intellectual property in some countries.

Risks related to our dependence on third parties

We rely, and expect to continue to rely, on third parties to conduct some or all aspects of our product manufacturing, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.

We do not expect to independently conduct all aspects of our product manufacturing, research and preclinical and clinical testing. We currently rely, and expect to continue to rely, on third parties with respect to many of these items, including CMOs for the manufacturing of any product candidates we test in preclinical or clinical development, as well as CROs for the conduct of our animal testing and research. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study protocols. For example, for product candidates that we develop and commercialize on our own, we will remain responsible for ensuring that each of our IND-enabling studies and clinical trials are conducted in accordance with the study plan and protocols.

Although we intend to design the clinical trials for any product candidates we may develop, CROs will conduct some or all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct ongoing and future preclinical studies and clinical trials will also result in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- · have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- · undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs and other

third parties do not perform preclinical studies and ongoing and future clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of any product candidates we may develop may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs and other third parties, we could be required to repeat, extend the duration of or increase the size of any preclinical studies or clinical trials we conduct and this could significantly delay commercialization and require greater expenditures.

If third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the preclinical studies and clinical trials required to support future IND submissions and approval of any product candidates we may develop.

Manufacturing biologic products is complex and subject to product loss for a variety of reasons. We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of VERVE-101 and our other product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. We also rely on these third parties for packaging, labeling, sterilization, storage, distribution and other production logistics. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- · reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We or our third-party manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredients, or API, necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or API, including shortages caused by the purchase of such raw materials or API by our competitors or others. The failure of us or our third-party manufacturers to obtain the raw materials or API necessary to manufacture sufficient quantities of our product candidates may have a material adverse effect on our business.

Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. Our third-party manufacturers are subject to inspection and approval by regulatory authorities before we can commence the manufacture and sale of any of our product candidates, and thereafter subject to ongoing inspection from time to time. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in regulatory actions, such as the issuance of FDA Form 483 notices of observations, warning letters or sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Manufacturing biologic products, such as VERVE-101, is complex, especially in large quantities. Biologic products must be made consistently and in compliance with a clearly defined manufacturing process. Accordingly, it is essential to be able to validate and control the manufacturing process to assure that it is reproducible. The manufacture of biologics is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the product process. We have not yet scaled up the manufacturing process for any of our product candidates for potential commercialization. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product

candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could harm our results of operations and cause potential reputational damage. Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a source for bulk drug substance nor do we have any agreements with third-party manufacturers for long-term commercial supply. If any of our future contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement or be unable to reach agreement with an alternative manufacturer.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

If any third-party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates, and/or increase the product yield of its manufacturing, then our costs to manufacture the product candidate may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of any current or future product candidates that we may develop, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of the product. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the quality of the product, then we may not be able to meet the demands of our ongoing or future clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operation.

We have entered into collaborations, and may enter into additional collaborations, with third parties for the research, development, manufacture and commercialization of programs or product candidates. If these collaborations are not successful, our business could be adversely affected.

As part of our strategy, we have entered into collaborations and intend to seek to enter into additional collaborations with third parties for one or more of our programs or product candidates. For example, in April 2019, we entered into the Beam Agreement to exclusively license certain of Beam's base editing, gene editing and delivery technology against certain cardiovascular targets for use in our product candidates, which agreement was amended and restated in July 2022; in October 2020, we entered into the Acuitas Agreement to license from Acuitas its LNP delivery technology that we are using in VERVE-101; in October 2021 we entered into the Novartis Agreement to license from Novartis certain lipid technology that we are using in VERVE-201; and in July 2022, we entered into the Vertex Agreement for a four-year worldwide research collaboration focused on developing in vivo gene editing candidates toward an undisclosed target for the treatment of a single liver disease. Our likely collaborators for any other collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We have under the Beam Agreement, and we may have under any other arrangements that we may enter into with any third parties, limited control over the amount and timing of resources that collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements may depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators. Collaborations pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based
 on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as
 an acquisition, that divert resources or create competing priorities;

- collaborators may not pursue commercialization of any product candidates that achieve regulatory approval or may elect not to continue
 or renew commercialization programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or
 available funding, or external factors, such as an acquisition, that may divert resources or create competing priorities;
- collaborators may delay preclinical studies and clinical trials, provide insufficient funding for a preclinical study or clinical trial program, stop a preclinical study or clinical trial or abandon a product candidate, repeat or conduct new preclinical studies or clinical trials or require a new formulation of a product candidate for preclinical or clinical testing;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates on a discretionary basis;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product
 candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be
 commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not
 commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the
 preferred course of development, might cause delays or terminations of the research, development or commercialization of product
 candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any
 of which would be time-consuming and expensive;
- collaborators may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may
 expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any current or future collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this "Risk Factors" section also apply to the activities of our collaborators.

Collaboration agreements may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. For example, upon execution of the Beam Agreement, we issued 276,075 shares of our common stock to Beam and in connection with the execution of the Vertex Agreement, we completed a private placement with Vertex pursuant to which we issued 1,519,756 shares of our common stock to Vertex. In addition, under the Cas9 License Agreement, we issued 138,037 shares of our common stock to Broad and Harvard. Broad and Harvard also had anti-dilution rights, pursuant to which we issued Broad and Harvard an additional 309,278 shares of our common stock in the aggregate following the completion of preferred stock financings. We also issued 878,098 additional shares of common stock to Broad and Harvard upon the closing of our IPO pursuant to the Cas9 License Agreement. We are also obligated to pay to Harvard and Broad tiered success payments in the event our average market capitalization exceeds specified thresholds ascending from a high nine-digit dollar amount to \$10.0 billion, or sale of our company for consideration in excess of those thresholds. In the event of a change of control of our company or a sale of our company, we are required to pay any related success payment in cash within a specified period following such event. Otherwise, the success payments may be

settled at our option in either cash or shares of our common stock, or a combination of cash and shares of our common stock. In September 2021, we notified Harvard and Broad that our average market capitalization exceeded three specified thresholds as of a relevant measurement date and aggregate success payments of approximately \$6.3 million became payable under the Cas9 License Agreement, which we settled in cash in November 2021.

We could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of several factors. If we license rights to any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

Additionally, subject to its contractual obligations to us, if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

If we are not able to establish or maintain collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans and our business could be adversely affected.

We face significant competition in attracting appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or other regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, the terms of any existing collaboration agreements, and industry and market conditions generally. The collaborator may also have the opportunity to collaborate on other product candidates or technologies for similar indications and will have to evaluate whether such a collaboration could be more attractive than the one with us for our product candidate.

We may also be restricted under existing or future license agreements from entering into agreements on certain terms with potential collaborators.

Collaborations are complex and time-consuming to negotiate, document and execute. In addition, consolidation among large pharmaceutical and biotechnology companies has reduced the number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market.

We depend on single-source suppliers for some of the components and materials used in our product candidates.

We depend on single-source suppliers for some of the components and materials used in our product candidates. We cannot ensure that these suppliers or service providers will remain in business, have sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of raw materials, components, key processes and finished goods exposes us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or

service provider could lead to supply delays or interruptions, which would damage our business, financial condition, results of operations and prospects.

If we have to switch to a replacement supplier, the manufacture and delivery of any product candidates we may develop could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers, if required, may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single source components and materials used in our products, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our product candidates.

Risks related to our intellectual property

If we or our licensors are unable to obtain, maintain, defend and enforce patent rights that cover our gene editing technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

Our success depends in large part on our ability to obtain, maintain, defend, and enforce protection of the intellectual property we may own solely and jointly with others or may license from others, particularly patents, in the United States and other countries with respect to proprietary technology and product candidates we develop. It is difficult and costly to protect our gene editing technologies and product candidates, and we may not be able to ensure their protection. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, importing or otherwise commercializing our product candidates we may develop, or operatively similar products, is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates that are important to our business and by in-licensing intellectual property related to our technologies and product candidates. If we are unable to obtain or maintain patent protection with respect to any proprietary technology or product candidate, our business, financial condition, results of operations and prospects could be materially harmed. Failure to obtain protection including patent protection, may be a result of specific legal and factual circumstances that may preclude the availability of protection for our product candidates in the United States or any given country. For example, inadequate, faulty or erroneous patent prosecution may result in diminution, loss or unavailability of patent rights that adequately cover our products. Patent disclosures and claims that are intended to cover our product candidates that are sufficient or allowable in one country may not be sufficient or allowable in another country. The requirements for filing a patent application in the United States may not be sufficient to support a patent filing in a country or region outside the United States.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce and defend the patents, covering technology that we license from third parties. Therefore, these in-licensed patents and applications may not be prepared, filed, prosecuted, maintained, defended and enforced in a manner consistent with the best interests of our business.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The field of gene editing especially has been the subject of extensive patenting activity and litigation. In addition, the scope of patent protection outside of the United States is uncertain and laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Further, no earlier than the second quarter of 2023, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation.

With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued

patents will provide sufficient protection from competitors. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates.

In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not published at all. Therefore, neither we nor our licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in-license now or in the future, or that either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned and in-licensed patent rights are highly uncertain. Moreover, our owned and in-licensed pending and future patent applications may not result in patents being issued which protect our technology and product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, could affect the value or narrow the scope of our patent rights.

Moreover, we or our licensors may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. Given the amount of time require for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our competitors may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology and products similar or identical to any of our technology and product candidates.

Our rights to develop and commercialize our gene editing technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

We depend on intellectual property licensed from third parties, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated, or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

We have licensed and are dependent on certain patent rights and proprietary technology from third parties that are important or necessary to the development of our gene editing technology and product candidates. For example, we are a party to the Beam Agreement, the Cas9 License Agreement, the Acuitas Agreement, the Novartis Agreement, and other license agreements, pursuant to which we in-license and have acquired key patents and patent applications for our gene editing technology, LNP technology and product candidates. These license agreements impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate our license, in which event we would not be able to develop or market our gene editing technology or product candidates covered by the intellectual property licensed under these agreements.

These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our gene editing technology and product candidates in the future. Some licenses and acquired patents granted to us are expressly subject to certain

preexisting rights held by the licensor or certain third parties. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in certain territories or fields. If we determine that rights to such excluded fields are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to continue developing, manufacturing or marketing our product candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our product candidates or allow our competitors or others the chance to access technology that is important to our business.

In addition, pursuant to the Cas9 License Agreement, under certain specific circumstances, Harvard and Broad may grant a license to the patents that are the subject of such license agreements to a third party in the same field as such patents are licensed to us. Such third party may then have full rights that are the subject of the Cas9 License Agreement, which could impact our competitive position and enable a third party to commercialize products similar to our potential future product candidates and technology. Any grant of rights to a third party in this scenario would narrow the scope of our exclusive rights to the patents and patent applications we have in-licensed from Harvard and Broad.

We do not have complete control in the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license or have acquired from third parties. It is possible that our licensors' enforcement of patents against infringers or defense of such patents against challenges of validity or claims of enforceability may be less vigorous than if we had conducted them ourselves, or may not be conducted in accordance with our best interests. We cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our product candidates we may develop that are the subject of such licensed rights could be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, the license granted to us in jurisdictions where the consent of a co-owner is necessary to grant such a license may not be valid and such co-owners may be able to license such patents to our competitors, and our competitors could market competing products and technology. In addition, our rights to our in-licensed patents and patent applications are dependent, in part, on inter-institutional or other operating agreements between the joint owners of such in-licensed patents and patent applications. If one or more of such joint owners breaches such inter-institutional or operating agreements, our rights to such in-licensed patents and patent applications may be adversely affected. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Furthermore, inventions contained within some of our in-licensed patents and patent applications were made using U.S. government funding. We rely on our licensors to ensure compliance with applicable obligations arising from such funding, such as timely reporting, an obligation associated with our in-licensed patents and patent applications. The failure of our licensors to meet their obligations may lead to a loss of rights or the unenforceability of relevant patents. For example, the U.S. government could have certain rights in such in-licensed patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. If the U.S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The U.S. government's rights may also permit it to disclose the funded inventions and technology to third parties and to exercise march-in rights to use or allow third parties to use the technology we have licensed that was developed using U.S. government funding. The U.S. government may also exercise its march-in rights if it determines that action is necessary because we or our licensors failed to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in such in-licensed U.S. government-funded inventions may be subject to certain requirements to manufacture product candidates embodying such inventions in the United States. Any of the foregoing could harm our business, financial condition, results of operations and prospects significantly.

In the event any of our third-party licensors determine that, in spite of our efforts, we have materially breached a license agreement or have failed to meet certain obligations thereunder, it may elect to terminate the applicable license agreement or, in some cases, one or more license(s) under the applicable license agreement, and such termination would result in us no longer having the ability to develop and commercialize product candidates and technology covered by that license agreement or license. In the event of such termination of a third-party in-license, or if the underlying patents under a third-party in-license fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our owned patent applications and in-licensed patents and patent applications and other intellectual property may be subject to priority or inventorship disputes, interferences and similar proceedings. If we or our licensors are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop, which could have a material adverse impact on our business.

Certain of the U.S. patents and one U.S. patent application to which we hold an option are co-owned by Broad and MIT, and in some cases co-owned by Broad, MIT and Harvard, which we refer to together as the Boston Licensing Parties, and were involved in U.S. Interference No. 106,048 with one U.S. patent application co-owned by the University of California, the University of Vienna, and Emmanuelle Charpentier, which we refer to together as CVC. On September 10, 2018, the Court of Appeals for the Federal Circuit, or the CAFC, affirmed the Patent Trial and Appeal Board of the USPTO's, or PTAB's, holding that there was no interference-in-fact. An interference is a proceeding within the USPTO to determine priority of invention of the subject matter of patent claims filed by different parties.

On June 24, 2019, the PTAB declared an interference (U.S. Interference No. 106,115) between 10 U.S. patent applications that are coowned by CVC, and 13 U.S. patents and one U.S. patent application (that are co-owned by the Boston Licensing Parties). In the declared interference, CVC has been designated as the junior party and the Boston Licensing Parties have been designated as the senior party. On February 28, 2022, the PTAB held that the Boston Licensing Parties had priority over CVC with respect to Count 1 of the interference: a single RNA CRISPR-Cas9 system that functions in eukaryotic cells. As a result, CVC's patent applications involved in this interference were deemed unpatentable.

On December 20, 2020, the PTAB declared an interference (U.S. Interference No. 106,126) between one U.S. patent application owned by Toolgen, Inc. and 14 U.S. patents and two U.S. patent applications that are co-owned by the Boston Licensing Parties. In the declared interference, Boston Licensing Parties have been designated as the junior party and Toolgen, Inc. has been designated as the senior party.

On June 21, 2021, the PTAB declared an interference (U.S. Interference No. 106,133) between one U.S. patent application owned by Sigma-Aldrich Co., LLC and 14 U.S. patents and two U.S. patent applications that are co-owned by the Boston Licensing Parties. In the declared interference, Boston Licensing Parties have been designated as the junior party and Sigma-Aldrich Co., LLC has been designated as the senior party

As a result of the declaration of interference, an adversarial proceeding in the USPTO before the PTAB has been initiated, which is declared to ultimately determine priority, specifically and which party was first to invent the claimed subject matter. An interference is typically divided into two phases. The first phase is referred to as the motions or preliminary motions phase while the second is referred to as the priority phase. In the first phase, each party may raise issues including but not limited to those relating to the patentability of a party's claims based on prior art, written description, and enablement. A party also may seek an earlier priority benefit or may challenge whether the declaration of interference was proper in the first place. Priority, or a determination of who first invented the commonly claimed invention, is determined in the second phase of an interference. Although we cannot predict with any certainty how long each phase will actually take, each phase may take approximately a year or longer before a decision is made by the PTAB. It is possible for motions filed in the preliminary motions phase to be dispositive of the interference proceeding, such that the second priority phase is not reached.

There can be no assurance that these pending U.S. interference proceedings will be resolved in favor of the Boston Licensing Parties. If the 106,126, or 106,133 interference resolves in favor of Toolgen, Inc. or Sigma-Aldrich Co., LLC, respectively, or if the Boston Licensing Parties' patents and patent application are narrowed, invalidated, or held unenforceable, we will lose the ability to license the optioned patents and patent application and our ability to commercialize our product candidates may be adversely affected if we cannot obtain a license to relevant third-party patents that cover our product candidates. We may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our gene editing technology or product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

We or our licensors may also be subject to claims that former employees, collaborators, or other third parties have an interest in our owned patent applications or in-licensed patents or patent applications or other intellectual property as an inventor or co-inventor. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patent applications, such co-owners rights may be subject, or in the future subject, to assignment or license to other third parties, including our competitors. In addition, we may need the cooperation of any such co-owners to enforce any patents that issue from such patent applications against third parties, and such cooperation may not be provided to us.

If we or our licensors are unsuccessful in any interference proceedings or other priority, validity (including any patent oppositions) or inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more of our owned, licensed or optioned patents, or such patent claims may be narrowed, invalidated or held unenforceable, or through loss of exclusive ownership of or the exclusive right to use our owned or in-licensed patents. In the event of loss of patent rights as a result of any of these disputes, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and product candidates. Even if we or our licensors are successful in an interference proceeding, other similar priority disputes, or inventorship or ownership disputes, it could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects.

If we fail to comply with our obligations in our intellectual property licenses arrangements with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are party to agreements, and we may enter into additional arrangements, with third parties that may impose diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. We have existing agreements, pursuant to which we are obligated to pay royalties on net product sales of product candidates or related technologies to the extent they are covered by the agreements. If we fail to comply with such obligations under current or future agreements, our counterparties may have the right to terminate these agreements or require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects. While we still face all of the risks described herein with respect to those agreements, we cannot prevent third parties from also accessing those technologies. In addition, our licenses may place restrictions on our future business opportunities.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- · the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors
 and us and our partners; and
- · the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the intellectual property or intellectual property rights we in-license. If other third parties have ownership rights to intellectual property or intellectual property rights we in-license, they may be able to license such intellectual property or intellectual property or intellectual property or intellectual property rights to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

We currently have rights to intellectual property, through licenses from third parties, to identify and develop product candidates, and we expect to seek to expand our product candidate pipeline in part by in-licensing the rights to key technologies. Although we have succeeded in licensing technologies from third-party licensors including Harvard, Broad, Beam, Acuitas and Novartis in the past, we cannot assure our stockholders that we will be able to in-license or acquire the rights to any product candidates or technologies from third parties on acceptable terms or at all.

Various third parties practice in competitive technology areas and may have issued patents or patent applications that will issue as patents in the future, which could impede or preclude our ability to commercialize our product candidates. For any third-party patents that could be relevant to our product candidates, we rely in part on the "safe harbor" or research exemption under 35 U.S.C. § 271(e)(1), which exempts from patent infringement activities related to pursuing FDA approval for a drug product. However, while U.S. patent law provides such a "safe harbor" to our clinical product candidates under this provision, that exemption expires when an IND or BLA is submitted. Given the uncertainty of clinical trials, we cannot be certain of the timing of their completion and it is possible that we may submit a BLA for one of our product candidates at a time when one or more relevant third-party patents is in force.

It may therefore be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

Furthermore, there has been extensive patenting activity in the field of gene editing, and pharmaceutical companies, biotechnology companies, and academic institutions are competing with us or are expected to compete with us in the field of gene editing technology and filing patent applications potentially relevant to our business, and there may be third-party patent applications that, if issued, may allow the third party to circumvent our patent rights. Because of the large number of patents issued and patent applications filed in our field, these and other third parties could allege they have patent rights encompassing our product candidates, technologies or methods. In order to market our product candidates, we may find it necessary or prudent to obtain licenses from such third-party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for product candidates and gene editing technology we may develop. We may also require licenses from third parties for certain gene editing technologies including certain delivery and gene editing compositions and methods that we are evaluating, or may in the future evaluate, for use with product candidates we may develop. In addition, some of our owned patent applications and in-licensed patents and patent applications may be determined to be co-owned with third parties. With respect to any patents co-owned with third parties, we may require licenses to such co-owners' interest to such patents. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such coowners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

In addition, the licensing or acquisition of third-party intellectual property rights is a highly competitive area, and a number of more established companies are also pursuing strategies to license or acquire third party intellectual property rights that

we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Additionally, if we fail to comply with our obligations under license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

The intellectual property landscape around genome editing technology, including base editing, is highly dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent, delay or otherwise interfere with our product discovery and development efforts.

Our commercial success depends upon our ability and the ability of our collaborators to research, develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. The field of genome editing, especially in the area of base editing technology, is still in its infancy, and no such product candidates have reached the market. Due to the intense research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is evolving and in flux, and it may remain uncertain for the coming years. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. There may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed, and other third party, intellectual property and proprietary rights in the future. We may be subject to and may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our gene editing platform technology and any product candidates we may develop, including interference proceedings, post-grant review, inter partes review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office. Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our product candidates and they may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit.

As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our gene editing technology and product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of therapies, products or their methods of use or manufacture. We are aware of certain third-party patent applications that, if issued, may be construed to cover our gene editing technology and product candidates. There may also be third-party patents of which we are currently unaware with claims to technologies, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

It is possible that we have failed to identify relevant third-party patents or applications that our product candidates and programs may infringe. Because patent applications can take many years to issue, may be confidential for 18 months or more after filing and can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use, sale or importation of any product candidates we may develop or our technology, and we may not be aware of such patents. Furthermore, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States may remain confidential until a patent issues. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to any product candidates we may develop and our technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, any product candidates we may develop or the use of any product candidates we may develop.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could adversely affect our ability to commercialize our product candidates or any other of our product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. Our product candidates make use of CRISPR-based gene editing technology, which is a field that is highly active for patent filings. The extensive patent filings related to CRISPR and Cas make it difficult for us to assess the full extent of relevant patents and pending applications that may cover our gene editing technology and product candidates and their use or manufacture. There may be third-party patents or patent applications, including patents held or controlled by our competitors with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our gene editing technology and product candidates.

If we are found to infringe, misappropriate or otherwise violate a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right indemnify our customers or collaborators. A finding of infringement could prevent us from manufacturing and commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed

patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our product candidates may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for any product candidates we may develop, our business may be materially harmed.

In the United States, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under clinical development and regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to and that covers an approved drug may be extended. Similar provisions are available in Europe, such as supplementary protection certificates, and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering any of our product candidates that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our gene editing platform technology and product candidates.

As is the case with other biotech and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Past U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future. For example, in the case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that claims to certain DNA molecules are not patentable. More recently, in *Amgen Inc. v. Sanofi*, the Federal Circuit held that claims with functional language may pose high hurdles in fulfilling the enablement requirement for claims with broad functional language. We cannot predict how this and future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition, results of operations and prospects.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court. We may not be able to protect our trade secrets in court.

If we or one of our licensing partners initiates legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term, including a patent term adjustment granted by the USPTO, if a terminal disclaimer is filed to obviate a finding of obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which the patent examiner and we or our licensing partners were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenfor

lose at least part, and perhaps all, of the patent protection on one or more of our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect, and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our owned and in-licensed patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we may rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on outside firms and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business, financial condition, results of operations and prospects.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property and proprietary rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, we may not be able to prevent third parties from practicing our inventions in

all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Furthermore, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our licensed patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have a predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of third parties, or we have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the

ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial conditions, results of operations and prospects.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants, but we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. In addition, trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any of that information was independently developed by a competitor, our competitive position could be harmed.

In addition, some courts inside and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Any registered trademarks or trade names may be challenged, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- any product candidates we may develop will eventually become commercially available in generic or biosimilar product forms;
- others may be able to make gene editing product that are similar to ours but that are not covered by the claims of the patents that we own:
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our pending owned and in-licensed patent applications or those we may own or in-license in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our owned or in-licensed patents, or parts of our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable:
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- the laws of foreign countries may not protect our proprietary rights or the proprietary rights of license partners or current or future collaborators to the same extent as the laws of the United States;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or
 processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as
 inventors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patent rights;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- · we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before our relevant patents that we own or license expire;
- · we may not develop additional proprietary technologies that are patentable;
- · the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks related to commercialization

Even if any of our current or future product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for any of such product candidates, if approved, may be smaller than we estimate.

If any of our current or future product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current CVD treatments such as statins, ezetimibe, bempedoic acid, lomitapide, mipomersen and icosapent ethyl are well-established in the medical community, and physicians may continue to rely on these treatments.

Even if VERVE-101, VERVE-201 or any other product candidate we develop meets its safety and efficacy endpoints in clinical trials, we cannot be certain that success in clinical trials will ensure success as a commercial product. For example, in September 2022, AstraZeneca and Ionis Pharmaceuticals, Inc. determined not to advance an antisense oligonucleotide PCKS9 inhibitor dosed once monthly via subcutaneous administration into Phase 3 clinical development for the treatment of hypercholesterolemia following a Phase 2b clinical trial that met its primary endpoint and achieved a statistically significant 62.3% reduction in LDL-C after 28 weeks compared to placebo on the basis that the results did not meet AstraZeneca's target product profile criteria to invest in a broad Phase 3 development program.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If our current or future product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our current or future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages of such product candidates compared to the advantages and relative risks of alternative treatments;
- · the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar biosimilar treatments;
- our ability to offer our products, if approved, for sale at competitive prices;
- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- · the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out of pocket for required copayments or in the absence of third-party coverage or adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products, if approved, together with other medications.

Our assessment of the potential market opportunity for our current or future product candidates is based on industry and market data that we obtained from industry publications, research, surveys and studies conducted by third parties and our analysis of these data, research, surveys and studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Our estimates of the potential market opportunities for our product candidates include a number of key assumptions based on our industry knowledge, industry publications and third-party research, surveys and studies, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for any of our product candidates may be smaller than we expect,

and as a result our revenues from product sales may be limited and it may be more difficult for us to achieve or maintain profitability.

We face substantial competition, which may result in others discovering, developing or commercializing products before us or more successfully than we do.

The development and commercialization of new drug or biologic products is highly competitive. It is particularly competitive with respect to new products for CVD, for which the standard of care is well-established. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of many of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are several approved products for low-density lipoprotein cholesterol, or LDL-C, lowering or cardiovascular risk reduction, such as statins, ezetimibe, bempedoic acid, lomitapide, mipomersen and icosapent ethyl.

There are several approved products that target PCSK9 protein as a mechanism to lower LDL-C and reduce the risk of ASCVD. Evolocumab, a monoclonal antibody, or mAb, marketed as Repatha by Amgen, is approved by the FDA for the treatment of patients with heterozygous familial hypercholesterolemia, or HeFH, patients with HoFH and in patients with ASCVD. Alirocumab, a mAb marketed as Praluent by Sanofi and Regeneron Pharmaceuticals, Inc., or Regeneron, is approved by the FDA for the treatment of patients with ASCVD and for the treatment of patients with primary hyperlipidemia, including HeFH. Regeneron has sole U.S. rights to alirocumab and Sanofi has sole ex-U.S. rights to alirocumab. The approved mAb treatments act through extracellular inhibition of PCSK9 protein. Inclisiran, a small interfering RNA, or siRNA, marketed as Leqvio by Novartis AG, is approved in the United States for the treatment of patients with clinical ASCVD or HeFH who require additional lowering of LDL-C and in Europe for the treatment of patients with hypercholesterolemia, including HeFH, or mixed dyslipidemia. Inclisiran acts by inhibiting the synthesis of PCSK9 within liver cells, which is distinct from extracellular protein inhibition

We are aware of several product candidates in clinical development that target PCSK9 protein as a mechanism to lower LDL-C and reduce the risk of ASCVD, including peptide-based anti PCSK9 vaccination, small molecule oral PCSK9 inhibitors, small binding proteins, and antisense oligonucleotides. In 2021, Esperion in-licensed an oral small molecule PCSK9 inhibitor from Serometrix LLC for which it disclosed plans to submit an IND in 2022, and MK-0616, an oral PCSK9 inhibitor being developed by Merck & Co., for which they plan to progress to Phase 2 for the treatment of hypercholesterolemia in 2022.

We are aware of one other gene editing program targeting the PCSK9 gene in preclinical development. Precision Biosciences, Inc., or Precision, has published preclinical data showing long-term stable reduction of LDL-C levels in non-human primates following *in vivo* gene editing of the PCSK9 gene using its gene editing platform. In September 2021, Precision entered into a collaboration with iECURE under which iECURE plans to advance Precision's PCSK9-directed nuclease product candidate into Phase 1 clinical trials for the treatment of familial hypercholesterolemia in 2022.

Evinacumab, a mAb targeting ANGPTL3 protein that is marketed by Regeneron, is approved by the FDA for the treatment of patients with HoFH. Evinacumab is also being evaluated by Regeneron in Phase 2 development for severe hypertriglyceridemia.

We are aware of several product candidates in clinical development that target ANGPTL3 protein as a mechanism to lower LDL-C and reduce the risk of ASCVD, including vupanorsen, an antisense oligonucleotide therapy being evaluated in a Phase 2 clinical trial by Ionis Pharmaceuticals, Inc. and Pfizer for the treatment of patients with elevated non-high-density lipoprotein cholesterol and triglycerides. ARO-ANG3, a siRNA targeting ANGPTL3 protein, is being evaluated in a Phase 1/2 clinical trial by Arrowhead Pharmaceuticals, Inc., or Arrowhead. In 2021, Arrowhead initiated a Phase 2b trial of ARO-ANG3 for the treatment of patients with mixed dyslipidemia. In addition, Eli Lilly and Company, or Eli Lilly, is evaluating a siRNA targeting ANGPTL3 protein in a Phase 1 study for the treatment of CVD.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or

other third-party payors seeking to encourage the use of biosimilar products. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive biosimilar products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our current and future product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience as a company with the commercialization of products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish a sales, marketing and distribution organization, either ourselves or through collaborations or other arrangements with third parties.

In the future, we expect to build a sales and marketing infrastructure to market some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the inability of reimbursement professionals to negotiate arrangements for coverage, formulary access, reimbursement and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and we enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We currently rely, and expect to continue to rely, on CMOs to manufacture our product candidates. If we are unable to enter into such arrangements as expected or if such organizations do not meet our supply requirements, development and/or commercialization of our product candidates may be delayed.

We currently rely, and expect to continue to rely, on third parties to manufacture clinical supplies of our product candidates and commercial supplies of our products, if and when approved for marketing by applicable regulatory authorities, as well as for packaging, sterilization, storage, distribution and other production logistics. If we are unable to enter into such arrangements on the terms or timeline we expect, development and/or commercialization of our product candidates may be delayed. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with regulatory requirements, if there are disagreements between us and such parties or if such parties are unable to expand capacities to support commercialization of any of our product candidates for which we obtain marketing approval, we may not be able to fulfill, or may be delayed in producing sufficient product candidates to meet, our supply requirements. These facilities may also be affected by catastrophic events, including pandemics, including the ongoing COVID-19 pandemic, terrorist attacks, wars or other armed conflicts, geopolitical tensions, such as the ongoing conflict between Russia and Ukraine, natural disasters, such as floods or fire, or such facilities could face manufacturing issues, such as contamination or regulatory concerns following a regulatory inspection of such facility. In such instances, we may need to locate an appropriate replacement third-party facility and establish a contractual relationship, which may not be readily available or on acceptable terms, which would cause additional delay and increased expense, including as a result of additional required FDA approvals, and may have a material adverse effect on our business.

Our third-party manufacturers will be subject to inspection and approval by the FDA before we can commence the manufacture and sale of any of our product candidates, and thereafter subject to FDA inspection from time to time. Failure by our third-party manufacturers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidates may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses.

We or our third-party manufacturers may also encounter shortages in the raw materials or API necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or API, including shortages caused by the purchase of such raw materials or API by our competitors or others. The failure of us or our third-party manufacturers to obtain the raw materials or API necessary to manufacture sufficient quantities of our product candidates may have a material adverse effect on our business.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- · a covered benefit under its health plan;
- safe, effective and medically necessary;
- · appropriate for the specific patient;
- cost-effective; and

· neither experimental nor investigational.

In the United States, there is no uniform policy of coverage and reimbursement for products that exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for our product candidates, if approved, by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require patient out-of-pocket costs that patients find unacceptably high.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

There can be no assurance that our product candidates, even if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, or that coverage and an adequate level of reimbursement will be available or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that, if they materialize, could harm our business.

Our future profitability will depend, in part, on our ability to commercialize our product candidates in markets outside of the United States. If we commercialize our product candidates in foreign markets, we will be subject to additional risks and uncertainties, including:

- · economic weakness, including inflation, or political instability in particular economies and markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- tariffs and trade barriers, as well as other governmental controls and trade restrictions;
- other trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or foreign governments;

- · longer accounts receivable collection times;
- · longer lead times for shipping;
- · compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is common;
- · language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of biosimilar alternatives to therapeutics;
- · foreign currency exchange rate fluctuations and currency controls;
- · differing foreign reimbursement landscapes;
- uncertain and potentially inadequate reimbursement of our products; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

If risks related to any of these uncertainties materializes, it could have a material adverse effect on our business.

Clinical trial and product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We will face an inherent risk of clinical trial and product liability exposure related to the testing of our product candidates in human clinical trials, and we will face an even greater risk if we commercially sell any products that we may develop. While we currently have no products that have been approved for commercial sale, the ongoing, planned and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- · termination of clinical trials;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial participants or patients;
- · loss of revenue;
- · reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently do not hold any clinical trial liability insurance coverage. We may need to obtain insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to obtain and maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Risks related to regulatory approval and other legal compliance matters

Gene editing is novel and the regulatory landscape that will govern any product candidates we may develop is uncertain and may change. As a result, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop.

The regulatory requirements that will govern any novel gene editing product candidates we develop are not entirely clear and may change. Within the broader genetic medicines field, we are aware of a limited number of gene therapy products that have received marketing authorization from the FDA and the EMA. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. Regulatory

requirements governing gene therapy products and cell therapy products have changed frequently and will likely continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials may also be subject to review and oversight by an IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

The same applies in the European Union. In the European Union, the development and evaluation of a gene therapy medicinal product must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. Additionally, for advanced therapy medicinal products, a marketing application authorization undergoes review by the EMA's Committee for Advanced Therapies, or CAT, in addition to review by the Committee for Medicinal Products for Human Use, or CHMP. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any product candidates we may develop, but that remains uncertain at this point.

Adverse developments in post-marketing experience or in clinical trials conducted by others of gene therapy products, cell therapy products, or products developed through the application of a base editing or other gene editing technology may cause the FDA, the EMA, and other regulatory bodies to revise the requirements for development or approval of any product candidates we may develop or limit the use of products utilizing base editing technologies, either of which could materially harm our business. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for novel product candidates such as the product candidates we may develop can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing base editing technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting products.

The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop.

Because we are developing product candidates in the field of genetic medicines, a field that includes gene therapy and gene editing, in which there is little clinical experience, there is increased risk that the FDA, the EMA, or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results and that these results may be difficult to analyze.

During the regulatory review process, we will need to identify success criteria and endpoints such that the FDA, the EMA, or other regulatory authorities will be able to determine the clinical efficacy and safety profile of any product candidates we may develop. As we are seeking to identify and develop product candidates to treat diseases in which there is no clinical experience using a gene editing approach, there is heightened risk that the FDA, the EMA, or other regulatory authorities may not consider the clinical trial endpoints that we propose to provide clinically meaningful results (reflecting a tangible benefit to patients). In addition, the resulting clinical data and results may be difficult to analyze. Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the prespecified endpoints to a degree of statistical significance. Further, even if we do achieve the pre-specified criteria, we may produce results that are unpredictable or inconsistent with the results of the non-primary endpoints or other relevant data. The FDA also weighs the benefits of a product against its risks, and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. Other regulatory authorities in the European Union and other countries may make similar comments with respect to these endpoints and data. Any product candidates we may develop will be based on a novel technology that makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval. No gene editing therapeutic product has been approved in the United States or in Europe.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of any product candidates we develop. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we develop, and our ability to generate revenue will be materially impaired.

Any product candidates we develop, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have no experience as a company in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to the various regulatory authorities for each therapeutic indication to establish the biologic product candidate's safety, purity and potency. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved and the specific disease or condition to be treated. Of the large number of products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. Even if any product candidates we may develop demonstrate safety and efficacy in clinical trials, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we develop, the commercial prospects for those product candidates may be harmed and our ability to generate revenues will be materially impaired.

Obtaining and maintaining marketing approval or commercialization of our product candidates in the United States does not mean that we will be successful in obtaining marketing approval of our product candidates in other jurisdictions. Failure to obtain marketing approval in foreign jurisdictions would prevent any product candidates we develop from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.

In order to market and sell any product candidates we may develop in the European Union and many other foreign jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying local regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our product candidates in any jurisdiction, which would materially impair our ability to generate revenue.

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020 and European Union rules and regulations ceased to apply to the United Kingdom starting on January 1, 2021. The Medicines and Healthcare products Regulatory Agency, or the MHRA, is now the sole decision maker for marketing authorizations of pharmaceutical products in the United Kingdom, except for Northern Ireland. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law of the United Kingdom the body of European Union law governing medicinal products that pre-existed before the United Kingdom's withdrawal from the European Union.

Since the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, the consequences of Brexit and the impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom remains unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business. As a result of Brexit, we expect we will need to submit a separate application to the MHRA for marketing approval in the United Kingdom, in addition to any planned marketing authorization applications for the EMA.

We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

We may seek certain designations for our product candidates, including Fast Track, Breakthrough Therapy, Regenerative Medicine Advanced Therapy and Priority Review designations in the United States, and PRIME Designation in the European Union, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical need for this condition, the sponsor may apply to the FDA for Fast Track designation. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective.

In addition, an applicant may seek designation of its product as a breakthrough therapy, which is a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

Additionally, a product is eligible for Regenerative Medicine Advanced Therapy, or RMAT, designation if it is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. The benefits of an RMAT designation are similar to a breakthrough therapy designation and include early interactions with the FDA to expedite development and review, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

Further, if the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

We may seek these and other designations for our product candidates. The FDA has broad discretion with respect to whether or not to grant these designations to a product candidate, so even if we believe a particular product candidate is

eligible for such designation or status, the FDA may decide not to grant it. Moreover, a Fast Track, breakthrough therapy or RMAT designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. As a result, while we may seek and receive these designations for our product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw these designations if it believes that the designation is no longer supported by data from our clinical development program.

In the European Union, we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the European Union or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the European Union and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME also encourages an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

We may not be able to obtain orphan drug exclusivity for any product candidates we may develop, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

In order for the FDA to grant orphan drug exclusivity to one of our products, the agency must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In particular, the concept of what constitutes the "same drug" for purposes of orphan drug exclusivity remains in flux in the context of gene therapies, and the FDA has issued recent final guidance suggesting that it would not consider two genetic medicine products to be different drugs solely based on minor differences in the transgenes or vectors. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

In 2017, the Congress passed the FDA Reauthorization Act of 2017, or the FDARA. FDARA, among other things, codified the FDA's preexisting regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. Under Omnibus legislation signed by President Trump on December 27, 2020, the requirement for a product to show clinical superiority applies to drugs and biologics that received orphan drug designation before enactment of FDARA in 2017, but have not yet been approved or licensed by FDA.

The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease

or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Negative public opinion of gene editing and increased regulatory scrutiny of gene editing and genetic research may adversely impact public perception of our future product candidates.

Our potential therapeutic products involve introducing genetic material into patients' cells. The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene editing and gene regulation for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene editing and gene regulation are unsafe, unethical or immoral, and, consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products once approved. For example, in 2003, trials using early versions of murine gamma-retroviral vectors, which integrate with, and thereby alter, the host cell's DNA, have led to several well-publicized adverse events, including reported cases of leukemia. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. The risk of cancer remains a concern for gene editing, and we cannot assure that it will not occur in any of our planned or future clinical trials. If any such adverse events occur, commercialization of our product candidates or further advancement of our clinical trials could be halted or delayed, which would have a negative impact on our business and operations.

Even if we, or any collaborators we may have, obtain marketing approvals for any product candidates we develop, the terms of approvals and ongoing regulation of our products could require the substantial expenditure of resources and may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The FDA typically advises that patients treated with genetic medicine undergo follow-up observations for potential adverse events for up to a 15-year period. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

Accordingly, assuming we, or any collaborators we may have, receive marketing approval for one or more product candidates we develop, we, and such collaborators, and our and their contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control. If we and such collaborators are not able to comply with post-approval regulatory requirements, we and such collaborators could have the marketing approvals for our products withdrawn by regulatory authorities and our, or such collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition, and prospects.

Any product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

The FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Although physicians may prescribe products for uses not described in the product's labeling, known as off-label uses, in their professional medical judgment, the FDA and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products, if approved, in a manner inconsistent with their approved labeling, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice, or DOJ. Violation of the Federal Food, Product, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws. In September 2021, the FDA published final regulations that describe the types of evidence that the FDA will consider in determining the intended use of a drug or biologic.

In addition, later discovery of previously unknown problems with our product candidates, manufacturers, or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers, or manufacturing processes;
- · restrictions on the labeling or marketing of a medicine;
- · restrictions on the distribution or use of a medicine;
- requirements to conduct post-marketing clinical trials;
- receipt of warning or untitled letters;
- · withdrawal of the medicines from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- · recall of medicines;
- fines, restitution, or disgorgement of profits or revenue;
- · suspension or withdrawal of marketing approvals;
- · suspension of any ongoing clinical trials;
- · refusal to permit the import or export of our medicines;
- product seizure: and
- · injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we develop and adversely affect our business, financial condition, results of operations, and prospects.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the Securities and Exchange Commission, or the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to the COVID-19 pandemic, a number of companies announced in 2021 receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Following a period of false starts and temporary suspensions due to the omicron variant, the FDA resumed domestic inspections in February 2022 and indicated that it would conduct foreign inspections beginning in April 2022 on a prioritized basis However, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Any relationships we may have with customers, healthcare providers and professionals, and third-party payors, among others, will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties, including criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any products for which we are able to obtain marketing approval. Any arrangements we have with healthcare providers, third-party payors and customers will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations. The laws and regulations may constrain the business or financial arrangements and relationships through which we conduct clinical research, market, sell and distribute any products for which we obtain marketing approval. These include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering,
 receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or
 the purchase, order, or recommendation of, any good or service, for which payment may be made under federal and state healthcare
 programs such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower
 or qui tam actions, and civil monetary penalty laws impose civil and criminal penalties against individuals or entities for knowingly
 presenting or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other
 government payers that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to
 the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and
 willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or
 fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any
 healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering
 up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery
 of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as further amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, which imposes
 certain requirements, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare
 clearinghouses and certain healthcare providers, as well as their respective business associates and their subcontractors that perform
 services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and
 transmission of such individually identifiable health information;

- the federal transparency requirements under the federal Physician Payments Sunshine Act, which requires certain manufacturers of
 drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services, or HHS, information related to
 payments and other transfers of value to physicians, as defined by such law, and teaching hospitals and other covered recipients and
 ownership and investment interests held by healthcare providers and their immediate family members and applicable group purchasing
 organizations, and, beginning in 2022, will require applicable manufacturers to report information regarding payments and other transfers
 of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse
 anesthetists, anesthesiologist assistants, and certified nurse midwives; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing
 arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private
 insurers, and certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance
 guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to
 report information related to drug pricing and payments to physicians and other healthcare providers or marketing expenditures and state
 and local laws that require the registration of sales representatives; and state and foreign laws governing the privacy and security of
 health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by
 HIPAA, thus complicating compliance efforts.

Efforts to ensure that any business arrangements we have with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell or commercialize any product candidate for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

In March 2010, President Obama signed into law the PPACA. In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, which went into effect in April 2013 and will remain in effect through 2031. Pursuant to the CARES Act and subsequent legislation, these Medicare sequester reductions were suspended through the end of June 2022 but the full 2% cut resumed thereafter on July 1, 2022. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Since enactment of the PPACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, the Tax Act repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in

2019. Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the PPACA is an essential and inseverable feature of the PPACA, and therefore because the mandate was repealed as part of the Tax Act, the remaining provisions of the PPACA are invalid as well. However, on June 17, 2021, the-U.S. Supreme Court dismissed the case and sustained the PPACA. Litigation and legislation over the PPACA are likely to continue, with unpredictable and uncertain results.

The former Trump presidential administration also took executive actions to undermine or delay implementation of the PPACA, including directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden revoked those orders and issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this Executive Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the PPACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the PPACA; and policies that reduce affordability of coverage or financial assistance, including for dependents. This Executive Order also directs the HHS to create a special enrollment period for the Health Insurance Marketplace in response to the COVID-19 pandemic.

We expect that these healthcare reform measures, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions is subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, reduce the prices of pharmaceuticals under Medicare and Medicaid. Congress continues to consider various legislative measures to limit the costs of prescription drugs, including authorizing Medicare to negotiate the prices of certain pharmaceuticals with manufacturers each year, capping beneficiary out-of-pocket Part D drug costs at \$2,000 a year, and penalizing drug manufacturers for price hikes that outpace inflation.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the

cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, European Union and United Kingdom. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached certain contracts with our business partners. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In 2018, California passed into law the CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. On November 3, 2020, California voters passed the CPRA, which will significantly expand the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. Most CPRA provisions will take effect on January 1, 2023, though the obligations will apply to any personal information collected after January 1, 2022. These provisions may apply to some of our business activities. In addition, other states, including Virginia and Colorado, already have passed state privacy laws. Other states will be considering these laws in the future. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices

requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR places restrictions on the cross-border transfer of personal data from the European Union to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the European Union to other countries. In July 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU's decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. While we were not self-certified under the EU-U.S. Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States generally and increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners.

Following the withdrawal of the United Kingdom from the European Union, the United Kingdom's Data Protection Act 2018, which "implements" and complements the GDPR and achieved Royal Assent on May 23, 2018, applies to the-processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. While the Data Protection Act of 2018 is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under GDPR. The United Kingdom has already determined that it considers all European Union and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom to the European Union and EEA remain unaffected. In addition, a recent decision from the European Commission appears to deem the United Kingdom as being "essentially adequate" for purposes of data transfer from the European Union to the United Kingdom, although this decision may be re-evaluated in the future.

Beyond GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and any eventual sale and distribution of commercial products, through increased compliance costs, costs associated with contracting and potential enforcement actions.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business, financial condition, results of operations or prospects.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, vendors, consultants and partners, and, for our clinical trials, our principal investigators and CROs. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the European Commission, and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply

with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

We are subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the DOJ. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA and other anti-corruption laws potentially applicable to our business is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the compliance with the FCPA and other anti-corruption laws presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We are also subject to other laws and regulations governing our international operations, including applicable export control laws, economic sanctions on countries and persons, and customs requirements. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain drugs and drug candidates outside of the United States, which could limit our growth potential and increase our development costs.

There is no assurance that we will be completely effective in ensuring our compliance with the FCPA and other applicable anti-corruption, export, sanctions, and customs laws. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violations of these laws, including the FCPA, can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If we or any third-party manufacturer we engage now or in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could have a material adverse effect on our business.

We and third-party manufacturers we engage now are, and any third-party manufacturer we may engage in the future will be, subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance

may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

Risks related to employee matters and managing growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical, financial, operational and other business expertise of Sekar Kathiresan, M.D., our chief executive officer, Andrew Ashe, J.D., our president, chief operating officer and general counsel, Allison Dorval, our chief financial officer, and Andrew Bellinger, M.D., Ph.D., our chief scientific officer and chief medical officer, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing personnel will also be critical to our success.

The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Our success also depends on implementing and maintaining internal controls and the accuracy and timeliness of our financial reporting. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical, regulatory affairs, manufacturing and quality control and, if any of our product candidates receive marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Future acquisitions or strategic alliances could disrupt our business and harm our financial condition and results of operations.

We may acquire additional businesses, technologies or assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products or product candidates resulting from a strategic alliance or acquisition that may delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure our stockholders that, following any such acquisition, we will achieve the expected synergies to justify the transaction. The risks we face in connection with acquisitions include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- · coordination of research and development efforts;
- · retention of key employees from the acquired company;
- changes in relationships with collaborators as a result of product acquisitions or strategic positioning resulting from the acquisition;
- cultural challenges associated with integrating employees from the acquired company into our organization;
- the need to implement or improve controls, procedures and policies at a business that prior to the acquisition may have lacked sufficiently
 effective controls, procedures and policies;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violation of laws, commercial disputes, tax liabilities and other known liabilities;
- · unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions, cause us to incur unanticipated liabilities and harm the business generally. There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or results of operations.

Our internal information technology systems, or those of our collaborators, vendors or other contractors or consultants, may fail or suffer security breaches, loss of data and other disruptions, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, trigger contractual and legal obligations, potentially exposing us to liability, reputational harm or otherwise adversely affecting our business and financial results.

We are dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information, including but not limited to intellectual property, proprietary business information and personal information. It is critical that we, our vendors, collaborators or other contractors or consultants, do so in a secure manner to maintain the availability, security, confidentiality, privacy and integrity of such confidential information.

Despite the implementation of security measures, our internal information technology systems and those of any collaborators, vendors, contractors or consultants are vulnerable to damage or interruption from computer viruses, computer hackers, malicious code, employee error, theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, wars or other armed conflict, telecommunication and electrical failures or other compromise. There could be an increase in cybersecurity attacks generally as a result of the ongoing conflict between Russia and Ukraine and the resulting sanctions imposed by the United States and European governments, together with any additional future sanctions or other actions by them.

Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats.

The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. We cannot guarantee that the measures we have taken to date, and actions we may take in the future, will be sufficient to prevent any future breaches.

To the extent we experience a material system failure, accident, cyber-attack or security breach, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary or confidential information or other disruptions. For example, the loss of clinical trial data from ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our or our vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position and reputation could be harmed and the further development and commercialization of our product candidates could be delayed. As a result of such an event, we may be in breach of our contractual obligations. Furthermore, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

The financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we maintain and could have a material adverse effect on our business, financial condition, results of operations or prospects. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above.

Risks related to ownership of our common stock and our status as a public company

Our executive officers, directors and their affiliates, if they choose to act together, will have the ability to significantly influence all matters submitted to stockholders for approval.

Our executive officers and directors and their affiliates, in the aggregate, beneficially owned shares representing approximately 21.6% of our common stock as of November 3, 2022. As a result, if these stockholders were to choose to act together, they would effectively be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, could significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of ownership control may:

- · delay, defer or prevent a change in control;
- · entrench our management and board of directors; or
- delay or prevent a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to

replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- · limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that
 would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by
 our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our restated certificate of incorporation or amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

An active trading market for our common stock may not continue to develop or be sustained.

Our common stock began trading on the Nasdaq Global Select Market on June 17, 2021. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares may not continue to develop or be sustained. If an active market for our common stock does not continue to develop or is not sustained, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares, or at all.

If securities analysts do not publish or cease publishing research or reports or publish misleading, inaccurate or unfavorable research about our business or if they publish negative evaluations of our stock, the price and trading volume of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analysts will provide favorable coverage. Although we have obtained analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, or provides more favorable relative recommendations about our competitors, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

The price of our common stock has been volatile and may fluctuate substantially, which could result in substantial losses for our stockholders.

Our stock price has been and is likely to continue to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price they paid for their shares. The market price for our common stock may be influenced by many factors, including:

- timing and results of or developments in preclinical studies and clinical trials of our product candidates or those of our competitors or potential collaborators;
- adverse regulatory decisions, including failure to receive regulatory approvals for any of our product candidates;
- · our success in commercializing our product candidates, if and when approved;
- · developments with respect to competitive products or technologies;

- · regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- · the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license products, product candidates, technologies, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- · variations in our financial results or the financial results of companies that are perceived to be similar to us;
- · sales of common stock by us, our executive officers, directors or principal stockholders, or others;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, such as the impact of the COVID-19 pandemic on our industry and market conditions;
- the other factors described in this "Risk factors" section.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Such litigation may also cause us to incur other substantial costs to defend such claims and divert management's attention and resources. Furthermore, negative public announcements of the results of hearings, motions or other interim proceedings or developments could have a negative effect on the market price of our common stock.

We have broad discretion in the use of our cash and cash equivalents and may not use them effectively.

Our management has broad discretion in the application of our cash and cash equivalents and could use such funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest these funds in a manner that does not produce income or that loses value.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Persons who were our stockholders prior to our IPO continue to hold a substantial number of shares of our common stock. If such persons sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline.

In addition, certain of our executive officers, directors and stockholders affiliated with our directors have entered or may enter into Rule 10b5-1 plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the executive officer, director or affiliated stockholder when entering into the plan, without further direction from the executive officer, director or affiliated stockholder. A Rule 10b5-1 plan may be amended or terminated in some circumstances. Our executive officers, directors and stockholders affiliated with our directors also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Moreover, holders of a substantial number of shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also filed a registration statement on Form S-8 to register all of the shares of common stock that we were able to issue under our equity compensation plans as of June 17, 2021 and we filed a registration statement on Form S-8 to register the additional 2,910,704 shares of our common stock that became

issuable under our equity compensation plans on January 1, 2022. Shares registered under these registration statements on Form S-8 can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates, vesting arrangements, and exercise of options.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an EGC until the end of 2026, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30 before that time or if we have annual gross revenues of \$1.07 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than \$1 billion of non-convertible debt over a three-year period. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding
 mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial
 statements;
- · reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any
 golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act permits an EGC to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an EGC.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management has devoted and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we have incurred and particularly after we are no longer an EGC, we will continue to incur significant legal, accounting and other expenses that we did not previously incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs, particularly as we hire additional financial and accounting employees to meet public company internal control and financial reporting requirements, and will make some activities more time-consuming and costly compared to when we were a private company. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our filing of an Annual Report on Form 10-K with the SEC for the year ended December 31, 2022. However, while we remain an EGC, we will not be required to include an attestation report on internal control over

financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

Our restated certificate of incorporation designates the Court of Chancery of the State of Delaware and the federal district courts of the United States of America as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- · any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders;
- any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or
- any action asserting a claim arising pursuant to any provision of our restated certificate of incorporation or amended and restated bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine.

These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find either exclusive forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could materially adversely affect our business, financial condition and results of operations.

General risk factors

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

Changes in tax law may adversely affect our business or financial condition. On December 22, 2017, the U.S. government enacted the Tax Act, which significantly reformed the Code. The Tax Act, as amended by the CARES Act, among other things, contains significant changes to corporate taxation, including reducing the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limiting the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), limiting the deduction for NOLs arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income in tax years beginning after December 31, 2020 and eliminating NOL carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such NOLs may be carried forward indefinitely and such NOLs arising in taxable years beginning before January 1, 2021 are generally eligible to be carried back up to five years), imposing a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, eliminating U.S. tax on foreign earnings (subject to certain important exceptions), allowing immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits.

In addition to the CARES Act, as part of Congress' response to the COVID-19 pandemic, economic relief legislation has been enacted in 2020 and 2021 containing tax provisions. Regulatory guidance under the Tax Act and such additional legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen their impact on our business and financial condition. Also, as a result of the changes in the U.S. presidential administration and control of the U.S. Senate, additional tax legislation may be enacted; any such additional legislation could have an impact on us. In addition, it is uncertain if and to what extent various states will conform to the Tax Act and additional tax legislation. We urge prospective investors in our common stock to consult with their legal and tax advisors with respect to any recently enacted tax legislation, or proposed changes in law, and the potential tax consequences of investing in or holding our common stock.

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets and uncertainty about economic stability. The global economy and financial markets may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the sanctions relating to Russia, may also adversely impact the financial markets and the global economy, and the economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for any product candidates we may develop and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Item 2. Unregistered sales of equity securities and use of proceeds

Recent sales of unregistered securities

During the period covered by this Quarterly Report on Form 10-Q, we did not issue any unregistered equity securities other than pursuant to transactions previously disclosed in our Current Reports on Form 8-K.

Use of proceeds from registered securities

On June 21, 2021, we completed our IPO pursuant to a Registration Statement on Form S-1 (File No. 333-256608), which was declared effective by the SEC on June 16, 2021 and Form S-1 (File No. 333-257158), which was filed pursuant to Rule 462(b) of the Securities Act and was declared effective by the SEC on June 16, 2021.

The net offering proceeds to us, after deducting underwriting discounts and offering expenses payable by us of \$25.1 million, were \$281.6 million. As of September 30, 2022, we had not used any of the net proceeds from the IPO. We have invested the net proceeds from the offering in money market funds and short-term investments. There has been no material change in our planned use of the net proceeds from our IPO as described in our final prospectus, dated June 16, 2021, filed with the SEC pursuant to Rule 424(b).

Item 6. Exhibits

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of Verve Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 21, 2021).
3.2	Amended and Restated Bylaws of Verve Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 21, 2021).
10.1	Open Market Sale Agreement SM , dated as of July 1, 2022, by and between the Registrant and Jefferies LLC (incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3, filed with the SEC on July 1, 2022).
10.2*+	Amended and Restated Collaboration and License Agreement, dated as of July 5, 2022, by and between the Registrant and Beam Therapeutics, Inc.
10.3*+	Strategic Collaboration and License Agreement, dated as of July 18, 2022, by and between the Registrant and Vertex Pharmaceuticals Incorporated.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

^{*} Filed herewith.

^{**} Furnished herewith

⁺ Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

VERVE THERAPEUTICS, INC.

Date: November 7, 2022 By: /s/ Sekar Kathiresan

Sekar Kathiresan, M.D. Chief Executive Officer Principal Executive Officer

Date: November 7, 2022 By: /s/ Allison Dorval
Allison Dorval

Chief Financial Officer
Principal Financial and Accounting Officer

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Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

AMENDED AND RESTATED COLLABORATION AND LICENSE AGREEMENT

by and between

VERVE THERAPEUTICS, INC.

and

BEAM THERAPEUTICS INC.

July 5, 2022

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AMENDED AND RESTATED COLLABORATION AND LICENSE AGREEMENT

This Amended and Restated Collaboration and License Agreement (this "Agreement") is effective as of July 5, 2022 (the "Restatement Effective Date") and is entered into by and between Verve Therapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware ("Verve") and Beam Therapeutics Inc., a corporation organized and existing under the laws of the State of Delaware ("Beam", collectively with Verve, the "Parties" and each, a "Party").

RECITALS:

WHEREAS, the Parties entered into that certain Collaboration and License Agreement, dated April 3, 2019 (the "Original Agreement Effective Date"), as amended by that certain letter agreement between the Parties dated July 12, 2019 (as so amended, the "Original Agreement");

- **WHEREAS**, in accordance with Section 16.9 of the Original Agreement, the Parties desire to restructure their relationship and amend and restate the Original Agreement as set forth herein, with the effect that the Original Agreement shall be superseded hereby as of the Restatement Effective Date (save as otherwise expressly stated herein);
- **WHEREAS**, the Parties desire to add [**] (as hereinafter defined) as a Licensed Target and be granted licenses, and an assignment of certain patent rights, by Beam in relation thereto;
 - **WHEREAS**, the Parties desire to remove [**] as Licensed Targets;
- **WHEREAS**, Verve or its Affiliates owns or controls certain technology related to gene editing and certain technology related to the Licensed Targets (as hereinafter defined) and to [**];
- **WHEREAS**, Beam or its Affiliates owns or controls certain technology related to DNA base editing and RNA base editing platforms, including technology with respect to guide RNAs;
- WHEREAS, for purposes of such collaboration, Verve desires to obtain a license under certain intellectual property, including the Beam Base Editor Technology, upon the terms and conditions set forth herein, and Beam desires to grant such a license; and
 - **WHEREAS,** Verve or its Affiliates owns or controls certain technology relating to [**] (as hereinafter defined);
- WHEREAS, Beam desires to obtain a license under certain intellectual property, and an assignment of certain patent rights, related to [**] to develop and commercialize [**] Products (as hereinafter defined), upon the terms and conditions set forth herein, and Verve desires to grant such a license and assignment;
- **WHEREAS**, the Parties desire to amend the licenses related to certain delivery technology that were contained in the Original Agreement and to clarify the structure of licenses relating to GalNAc, [**] and [**] (each, as hereinafter defined); and

WHEREAS, Verve and Beam desire to provide licenses to one another and to enter into a collaboration to develop and commercialize Products (as hereinafter defined) upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and cross-licenses herein contained, the receipt and sufficiency of which are hereby acknowledged, Verve and Beam hereby agree that the Original Agreement is hereby amended and restated in its entirety as of the Restatement Effective Date to read as follows:

Article 1 DEFINITIONS

Unless specifically set forth to the contrary in this Agreement, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below or, if not listed below, the meaning designated in this Agreement.

- **1.1** "AAA" shall have the meaning given to such term in <u>Section 15.8</u>.
- 1.2 [**].
- 1.3_"Act" shall mean, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., or the Public Health Research Act, 42 U.S.C. §§ 262 et seq., as such may be amended from time to time.
- **1.4** "Action" shall mean (a) any claim, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), or arbitration brought against a Party by any Third Party and (b) any claim, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), controversy, assessment, arbitration, investigation, hearing, charge, complaint, demand, notice or proceeding of, to, from, by or before any Governmental Authority with respect to a Party.
- 1.5 "Affiliate" shall, with respect to a Person, mean any entity directly or indirectly controlled by, controlling, or under common control with, such Person, but only for so long as such control shall continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means (a) possession, direct or indirect, of the power to direct or cause direction of the management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise), or (b) beneficial ownership of at least fifty percent (50%) (or the maximum ownership interest permitted by Applicable Law) of the voting securities or other ownership or general partnership interest (whether directly or pursuant to any option, warrant or other similar arrangement) or other comparable equity interests in an entity. Notwithstanding anything to the contrary in this Agreement, GV 2017, L.P. and any *bona fide* investment fund or management company controlled by, controlling, or under common control with GV 2017, L.P. shall not be deemed an Affiliate of Verve for purposes of this Agreement.
- 1.6 "Agreement" shall have the meaning given to such term in the preamble to this agreement.

- 1.7 "[**]" shall have the meaning given to such term in <u>Section [**]</u>.
- 1.8_"[**]" means, [**].
- **1.9_**"[**]" means the [**] listed on <u>Schedule [**</u>].
- **1.10_"Alliance Manager"** shall have the meaning given to such term in <u>Section 3.7.1</u>.
- **1.11**_[**].
- 1.12_"ANGPTL3" shall have the meaning given to such term in Section 1.125.
- **1.13_"Applicable Law"** means the applicable laws, rules and regulations, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities, that may be in effect from time to time in the Territory.
- **1.14_"Available"** means, with respect to a target or gene, that such target or gene is not, at the applicable time, the subject of (a) [**], (b) [**], or (c) [**].
- 1.15_"Base Editor" shall mean [**].
- 1.16_"Base Editor Product" shall mean a [**]."
- 1.17 "Beam" shall have the meaning given to such term in the preamble to this Agreement.
- **1.18_"Beam Base Editor Know-How**" shall mean, all Know-How, patentable or otherwise, which (a) is Controlled by Beam or its Affiliates and either (b) [**] or (c) [**].
- **1.19_"Beam Base Editor Patent Rights"** shall mean, subject to <u>Section 2.4.3(a)</u>, Patent Rights which (a) are Controlled by Beam or its Affiliates as of the Original Agreement Effective Date through the Term and Cover the composition or use of any [**] or (b) are Controlled by Beam or its Affiliates as of the Restatement Effective Date or during the Term and claim [**], in each case ((a) and (b)) (i) solely as to claims in such Patent Rights that Cover the foregoing and (ii) including any claims Covering [**]. As of the Restatement Effective Date, the patents and patent applications containing Beam Base Editor Patent Rights are those listed on <u>Schedule 1.19</u>.
- **1.20** "Beam Base Editor Technology" shall mean Beam Base Editor Know-How and Beam Base Editor Patent Rights.
- **1.21_"Beam C2C1 Know-How"** shall mean all Know-How, patentable or otherwise, which (a) is Controlled by Beam or its Affiliates and either (b) [**] or (c) [**].
- 1.22_"Beam C2C1 Patent Rights" shall mean, subject to Section 2.4.3(b), Patent Rights which (a) are Controlled by Beam or its Affiliates as of the Original Agreement Effective Date through the Term and Cover the [**] or (b) are Controlled by Beam or its Affiliates as of the Restatement Effective Date or during the Term and claim [**], in each case ((a) and (b)) (i) solely as to claims in such Patent Rights that Cover the foregoing and (ii) including

- any claims Covering [**]. As of the Restatement Effective Date, the patents and patents applications containing Beam C2C1 Patent Rights are those listed on <u>Schedule 1.22</u>.
- 1.23_"Beam C2C1 Technology" shall mean the Beam C2C1 Know-How and Beam C2C1 Patent Rights.
- **1.24_"Beam Collaboration Know-How"** shall mean all Know-How, patentable or otherwise, conceived, developed, generated or reduced to practice during the Original Agreement Term or the Term solely by Beam or its Affiliates or other persons acting on behalf of Beam through the Development, Commercialization or Manufacture of Licensed Products.
- **1.25_"Beam Collaboration Patent Rights"** shall mean Patent Rights which (a) as of the Restatement Effective Date or during the Term are Controlled by Beam or its Affiliates and (b) claim Beam Collaboration Know-How.
- **1.26** "Beam Collaboration Technology" shall mean Beam Collaboration Know-How and Beam Collaboration Patent Rights.
- **1.27** "Beam Indemnified Parties" shall have the meaning given to such term in Section 13.2.
- **1.28 "Beam Opt-In Option"** shall have the meaning given to such term in Section 5.1.
- **1.29 "Beam Opt-Out Date"** shall have the meaning given to such term in Section 5.3.
- **1.30 "Beam Opt-Out Option"** shall have the meaning given to such term in Section 5.3.
- **1.31** "Beam Product-Specific Know-How" shall mean (a) any Verve GalNAc Know-How that [**]; and (b) any Verve Lipid Know-How that [**].
- **1.32_"Beam Product-Specific Patent Right"** shall mean (a) any Verve GalNAc Patent Right [**]; and (b) any Verve Lipid Patent Right [**].
- 1.33 "Beam Surviving Sublicensee" shall have the meaning given to such term in Section 2.2.5.
- **1.34 "Beam Terminated Product"** shall have the meaning given to such term in <u>Section 14.6.1(b)</u>.
- 1.35_"Beam Third Party Agreement" shall have the meaning given to such term in Section 11.3.6.
- **1.36** "Beam-[**] Agreement" shall mean the License Agreement by and between [**] and Beam, dated as of [**], as such agreement may be amended from time to time in accordance with its terms.
- **1.37** "Beam-[**] Agreement" shall mean the License Agreement by and between [**] and Beam [**], dated as of [**], as such agreement may be amended from time to time in accordance with its terms.

- **1.38_"Beam-[**] Agreement"** shall mean the License Agreement by and between [**] and Beam dated as of [**], as such agreement may be amended from time to time in accordance with its terms.
- **1.39_"Beam-[**] Agreement"** shall mean the License Agreement by and between [**] and Beam, dated as of [**], as such agreement may be amended from time to time in accordance with its terms.
- **1.40** "[**]" shall have the meaning given to such term in <u>Section 1.36</u>.
- **1.41** "[**]" shall have the meaning given to such term in <u>Section 1.37</u>.
- **1.42** "[**]" shall have the meaning given to such term in <u>Section 11.5.2</u>.
- **1.43** "Business Day" means a day other than a Saturday, Sunday, or a bank or other public holiday in New York, New York, United States.
- **1.44** "C2C1" shall mean [**]."
- **1.45_"Calendar Quarter"** shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; <u>provided</u> that the first Calendar Quarter of the Term shall begin on the Restatement Effective Date and end on the last day of the then current Calendar Quarter and the last Calendar Quarter of the Term shall begin on the first day of such Calendar Quarter and end on the last day of the Term.
- **1.46_"Calendar Year"** shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31; <u>provided</u> that the first Calendar Year of the Term shall begin on the Restatement Effective Date and end on December 31 of the then current Calendar Year and the last Calendar Year of the Term shall begin on the first day of such Calendar Year and end on the last day of the Term.
- 1.47 "[**]" shall mean [**].
- 1.48_"Challenged Patent Right" shall have the meaning given to such term in Section 1.148.
- 1.49_"Change of Control" means, with respect to a Person, any of the following: (a) the sale or disposition of all or substantially all of the assets of such Person to a non-Affiliate of such Person, (b) the acquisition by a non-Affiliate of such Person, directly or indirectly, other than by an employee benefit plan (or related trust) sponsored or maintained by such Person or any of its Affiliates, of more than fifty percent (50%) of such Person's outstanding shares of voting capital stock or similar equity (e.g., capital stock entitled to vote generally for the election of directors), (c) the merger or consolidation of such Person with or into another corporation or entity, or (d) a liquidation or dissolution of such Person or any direct or indirect parent of such Person, excluding, in the case of (b) or (c) above, an acquisition or a merger or consolidation of a Person in which holders of shares of such Person's voting capital stock or similar equity immediately prior to the acquisition, merger or consolidation have more than fifty percent (50%) of the ownership of voting capital stock or similar

equity of the acquiring non-Affiliate or the surviving corporation or entity in such merger or consolidation, as the case may be, immediately after the merger or consolidation. Notwithstanding the foregoing, a Change of Control will not be deemed to occur on account of a sale of assets, merger or other transaction effected exclusively for the purpose of changing the corporate domicile or legal form of such Person.

1.50[**].

- **1.51_"Clinical Trial"** shall mean a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, or Phase IV Clinical Trial.
- **1.52_"Clinical Trial Data"** shall mean, with respect to a Product that is a Licensed Product or Collaboration Product, (a) all pharmacokinetic, clinical, safety and other similar data that relate to the Development of such Product, including all data and information related to any Clinical Trials of such Product (including all final reports and case report forms) and (b) all clinical test designs and operating records related to any Clinical Trial for such Product.
- **1.53** "Code" shall have the meaning given to such term in <u>Section 14.6.3</u>.
- 1.54_"Collaboration Marks" shall have the meaning given to such term in Section 12.10.1.
- **1.55_"Collaboration Product**" shall mean an Opt-In Product for which (a) Beam has elected the Beam Opt-In Option in accordance with <u>Section 5.1</u>, (b) Beam has not elected the Beam Opt-Out Option and (c) Verve has not elected the Verve Opt-Out Option.
- **1.56_"Collaboration Technology**" shall mean the Beam Collaboration Technology, the Verve Collaboration Technology and the Joint Collaboration Technology.
- **1.57_"Collaboration Territory**" shall mean (a) for Collaboration Products directed towards ANGPTL3 or PCSK9, the United States, its territories and possessions and (b) for Collaboration Products directed towards [**], worldwide.
- **1.58_"Collaboration Territory Revenue**" shall mean, for any given time period, [**]. Collaboration Territory Revenue in any given time period shall be determined on an accrual basis from the Parties' books and records maintained in accordance with GAAP.
- **1.59_"Commercial Operations**" means, with respect to any Person and a country, the promotion, marketing or selling of any pharmaceutical or biologic product in such country by such Person or its Affiliates, either itself or jointly with a Third Party.
- **1.60_"Commercialization Budget**" shall mean, with respect to a Collaboration Product in the Collaboration Territory, the budget for Shared Commercialization Costs included in the Commercialization Plan for such Collaboration Product.
- **1.61** "Commercialization Plan" shall have the meaning given to such term in Section 7.3.1.

- **1.62_"Commercialization Senior Officer**" shall mean, with respect to a Party, any officer designated under <u>Section 3.3.3</u> (or such officer's designee) that has the requisite decision-making authority and expertise within such Party to make decisions related to Commercialization under this Agreement.
- **1.63_"Commercialize"** shall mean to promote, market, distribute, sell and provide product support for a Product, and "**Commercializing**" and "**Commercialization**" shall have correlative meanings.
- **1.64_"Commercially Reasonable Efforts"** shall mean, with respect to the efforts and resources to be expended by a Party with respect to any objective, the efforts and resources [**]. It is anticipated that the level of effort to be expended in the use of Commercially Reasonable Efforts will change over time, including to reflect changes in the status of the Product and the countries (or markets) involved. For the avoidance of doubt, where a Party has an obligation to use Commercially Reasonable Efforts, the efforts of such Party and its Affiliates and sublicensees shall be considered in determining whether such Party has satisfied such obligation.
- 1.65_"Committee" shall mean the JSC and any Subcommittee.
- **1.66** "Competitor" means:
 - **1.66.1** with respect to Beam, [**]. An entity that is a Competitor under the foregoing clause (b) shall only be deemed a Competitor for so long as such control exists. [**]. Any such entity(ies) shall only be added to <u>Schedule 1.66.1</u> by mutual written agreement of the Parties.
 - **1.66.2** and with respect to Verve, a Third Party that is, or has an Affiliate that is, (i) developing or commercializing a Verve Competitive Product or (ii) engaged in a Verve Competitive Program.
- **1.67** "Confidential Information" shall have the meaning given to such term in Section 10.1.
- 1.68_"Control", "Controls" or "Controlled by" shall mean, with respect to any product, Patent Right or other tangible or intangible intellectual property right, the possession (whether by ownership or license, other than licenses granted pursuant to this Agreement) by a Party or its Affiliate of the ability to grant to the other Party access to, ownership of, or a license or sublicense under, such product, Patent Right, or other intellectual property without violating the terms of any agreement or other arrangement with any Third Party; provided, however, that notwithstanding anything in this Agreement to the contrary, any product, Patent Right, Know-How, regulatory filings or documentation, or other tangible or intangible intellectual property right Controlled by (a) a Future Acquirer of a Party or (b) a Third Party that becomes an Affiliate of a Party due to a Change of Control of such Party following the Restatement Effective Date will not be treated as "Controlled" by such Party or its Affiliate for purposes of this Agreement, except in each case for Collaboration Technology generated by a Party or its Affiliates.

- **1.69_"Co-Promote"** shall mean the joint promotion of a Product by Verve and Beam through their respective sales forces under a single trademark in the Collaboration Territory, but shall not include any Manufacturing activities or Development activities or any other actions undertaken with Regulatory Authorities in order to obtain or maintain Marketing Authorizations. "Co-Promotion" and "Co-Promoting" shall have a correlative meaning.
- 1.70 "Co-Promotion Agreement" shall have the meaning given to such term in Section 7.6.
- 1.71_"Cost of Goods Manufactured" shall mean, with respect to a Product, [**].
- 1.72_"Cost Report" shall have the meaning given to such term in Section 9.5.2(a).
- 1.73_"Covered" shall mean, with respect to a given product, process, method or service, that a Valid Claim would (absent a license thereunder or ownership thereof) be infringed (whether directly infringed or indirectly by induced or contributory infringement) by the making, using, selling, offering for sale, importation or other exploitation of such product, process, method or service. With respect to a claim of a pending patent application, "infringed" refers to activity that would infringe or be covered by such Valid Claim if it were contained in an issued patent. Cognates of the word "Covered" shall have correlative meanings.
- **1.74_"CPI"** shall mean, with respect to personnel located in the U.S., the Consumer Price Index All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index), and with respect to personnel located outside the U.S., (a) an equivalent index in a foreign country applicable to FTEs in such country, accounting if possible for the area in such country where the personnel are located, or (b) other inflation measure or rate agreed to by the Parties.

1.75[**].

- 1.76_"Detail" means, with respect to a Collaboration Product in the Collaboration Territory, a face-to-face contact between a sales representative and a physician or other medical professional licensed to prescribe drugs, during which a primary position detail (as defined in the Co-Promotion Agreement) or a secondary position detail (as defined in the Co-Promotion Agreement) is made to such person, in each case as measured by each Party's internal recording of such activity in accordance with the Co-Promotion Agreement; provided that such meeting is consistent with and in accordance with the requirements of Applicable Law and this Agreement. When used as a verb, "Detail" means to engage in a Detail.
- 1.77_"Develop" shall mean to research, develop, analyze, test and conduct preclinical, clinical and all other regulatory trials for a product, as well as any and all activities pertaining to manufacturing development, formulation development and lifecycle management, including new formulations and all other activities related to securing and maintaining Marketing Authorization for a product. "Developing" and "Development" shall have correlative meanings.

- **1.78** "Development Budget" shall mean, with respect to a Subsequent Development Plan for a Collaboration Product, the budget for Development activities for such Collaboration Product in the Territory under such Development Plan in the Major Markets, as may be amended from time to time by the JSC. Each Development Budget shall be itemized by general Development activity and the Party expected to incur such expense.
- 1.79 "Development Cost Report" shall have the meaning given to such term in Section 9.5.2(a).
- **1.80** "Development Plan" shall mean, on a Product-by-Product basis, the Initial Development Plan and the Subsequent Development Plan for such Product.
- **1.81_"Development Senior Officer**" shall mean, with respect to a Party, any officer designated under <u>Section 3.3.3</u> (or such officer's designee) that has the requisite decision-making authority and expertise within such Party to make decisions related to Development under this Agreement.
- **1.82** "Disclosing Party" shall have the meaning given to such term in <u>Section 10.1</u>.
- **1.83** "**Dispute**" shall have the meaning given to such term in <u>Section 15.7</u>.
- **1.84_"EMA"** shall mean the European Medicines Agency and any successor Regulatory Authority having substantially the same function.
- **1.85_"European Union"** means the organization of member states of the European Union, as it may be constituted from time to time during the Term.
- **1.86_"Existing Confidentiality Agreement"** shall have the meaning given to such term in <u>Section 10.6</u>.
- **1.87** "FDA" shall mean the United States Food and Drug Administration and any successor Regulatory Authority having substantially the same function.
- **1.88** "Field" shall mean the prevention or treatment of human diseases.
- **1.89** "First Commercial Sale" shall mean, with respect to a product in a country, [**].
- **1.90** "FTE" shall mean [**] hours of work devoted to or in support of Development or Commercialization activities under this Agreement that is carried out by one or more qualified employees, contract personnel or consultants of a Party, measured in accordance with such Party's normal time allocation practices.
- 1.91_"FTE Cost" shall mean, for any period, the FTE Rate multiplied by the number of FTEs in such period.
- **1.92_"FTE Rate**" shall mean, (a) for the period during the Term through the end of the first full Calendar Year, a rate of [**] U.S. Dollars (\$[**]) per FTE and [**].

- 1.93 "Fully Absorbed Standard Costs" shall mean, with respect to a Product, [**].
- **1.94** "Future Acquirer" shall mean, with respect to a Party, the non-Affiliate party to any Change of Control of such Party and such non-Affiliate Person's Affiliates immediately prior to the Change of Control.
- 1.95 "GAAP" shall mean United States generally accepted accounting principles, consistently applied.
- 1.96_"GalNAc" shall have the meaning given to such term in Schedule 1.96.
- 1.97_"GalNAc Opt-In Exercise Notice" shall have the meaning given to such term in Section 2.5.1.
- **1.98** "GalNAc Opt-In Right" shall have the meaning given to such term in Section 2.5.1.
- **1.99** "GalNAc Product" shall mean, on a country-by-country basis, any Base Editor Product Developed, Manufactured, or Commercialized by or on behalf of Beam, its Affiliates, or its/their sublicensees (other than Verve) (a) [**] and (b) (i) the making, using, selling, offering for sale, importing or exporting of which in the country in question is Covered by at least one Valid Claim of any Verve GalNAc Patent Rights or (ii) [**].
- **1.100** "GalNAc Target" shall have the meaning given to such term in Section 2.5.1.
- 1.101____"Gatekeeper" shall have the meaning given to such term in Section 2.5.2.
- **1.102**____"Governmental Authority" shall mean any United States federal, state or local, or any foreign, government or political subdivision thereof, or any multinational organization or authority, or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.
- 1.103 "[**]" has the meaning set forth in Section 1.39.
- **1.104**____"IND" shall mean an investigational new drug application, clinical trial authorization, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.
- 1.105____"Indemnified Party" shall have the meaning given to such term in Section 13.4.1.
- 1.106____"Indemnifying Party" shall have the meaning given to such term in Section 13.4.1.
- 1.107____"Independent Product" means any Base Editor Product or Nuclease Product that is not a Licensed Product.
- **1.108** "Indication" shall mean [**].

- 1.109____"Initial Development Plan" shall have the meaning given to such term in Section 4.3.1.
- **1.110** "**Initiate**" or "**Initiation**" shall mean, with respect to a Clinical Trial, the administration of the first dose to a human subject in such Clinical Trial.
- **1.111** "**Institution**" means each of [**].
- 1.112 [**].
- 1.113 "JCC" shall have the meaning given to such term in Section 3.6.1.
- **1.114** "**JDC**" shall have the meaning given to such term in <u>Section 3.5.1</u>.
- 1.116____"Joint Collaboration Patent Rights" shall mean Patent Rights claiming any Joint Collaboration Know-How.
- **1.117____"Joint Collaboration Technology"** shall mean the Joint Collaboration Know-How and Joint Collaboration Patent Rights.
- 1.118_____"JSC" shall have the meaning given to such term in <u>Section 3.3</u>.
- **1.119**____"Know-How" shall mean any invention, discovery, development, data, information, process, method, technique, trade secret, composition of matter, formulation, article of manufacture or other know-how, and any physical embodiments of any of the foregoing.
- **1.120** [**].
- 1.121_____"Licensed Base Editor Product" means, on a country-by-country basis, any Base Editor Product (a) [**], and (b) (i) the making, using, selling, offering for sale, importing or exporting of which in the country in question is Covered by at least one Valid Claim of the Beam Base Editor Patent Rights or (ii) was made, discovered, developed or determined to have utility through the use of any of the Beam Base Editor Technology. For clarity, a Licensed Base Editor Product can also be Covered by one or more Valid Claims of the Beam C2C1 Patent Rights or have been made, discovered, developed or determined to have utility through the use of the Beam C2C1 Technology.
- 1.122 "Licensed C2C1 Product" means, on a country-by-country basis, any Nuclease Product (a) the making, using, selling, offering for sale, importing or exporting of which in the country in question is Covered by at least one Valid Claim of the Beam C2C1 Patent Rights or (b) was made, discovered, developed or determined to have utility through the use of any of the Beam C2C1 Technology.

- 1.123 "Licensed GalNAc Target" shall have the meaning given to such term in Section 2.5.1.
- **1.124** "Licensed Product" means Licensed Base Editor Products and Licensed C2C1 Products.
- **1.125____**"Licensed Targets" shall mean the genes encoding Angiopoietin-like 3 ("ANGPTL3"), Proprotein convertase subtilisin/kexin type 9 serine protease ("PCSK9"), and [**].
- 1.126____"Licensee" shall have the meaning given to such term in Section 1.148.
- 1.127____"Licensor" shall have the meaning given to such term in <u>Section 1.148</u>.
- **1.128** "Lipid Technology Product" shall mean any Base Editor Product (a) the making, using, selling, offering for sale, importing or exporting of which in the country in question is Covered by at least one Valid Claim of any Verve Lipid Patent Rights or (b) that was made, discovered, developed or determined to have utility by Beam, its Affiliates or sublicensees through the use of any Verve Lipid Know-How.
- **1.129** "LNP" shall mean lipid nanoparticle.
- 1.130____"Losses" shall have the meaning given to such term in <u>Section 13.1</u>.
- 1.131____"[**]" shall have the meaning given to such term in Schedule 1.131.
- 1.132 "Major Market" means each of [**].
- 1.133 "Manufacture" or "Manufacturing" shall mean, with respect to a product, including components thereof, the receipt, handling and storage of materials, the manufacturing, processing, packaging and labeling (excluding the development of packaging and labeling components for Marketing Authorization), holding (including storage), quality assurance and quality control testing (including release) of such compound or product (other than quality assurance and quality control related to development of the manufacturing process, which activities shall be considered Development activities) and shipping of such product (or components thereof).
- **1.134** "Marketing Authorization" shall mean all approvals from the relevant Regulatory Authority necessary to market and sell a product in any country, including Pricing Approval if necessary.
- 1.135____ "Material Transfer Agreement" shall have the meaning given to such term in Section 2.7.5.
- **1.136** "[**]" shall mean [**].
- 1.137 "NDA" shall mean a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the Act, or similar application or submission for Marketing Authorization of a Product filed with a Regulatory Authority to obtain Marketing Authorization for a biological, pharmaceutical or diagnostic product in the applicable jurisdiction.

- **1.138** "**Net Sales**" shall mean [**].
- **1.139** "Nuclease Product" shall mean [**].
- 1.140____"Opt-In Information Package" shall have the meaning given to such term in Section 5.1.
- **1.141** "**Opt-In Product**" shall mean [**] (a) Licensed Product, (b) [**] other Nuclease Product or (c) [**] other Base Editor Product [**].
- 1.142 "Opt-Out Date" shall mean the Beam Opt-Out Date or the Verve Opt-Out Date, as applicable.
- 1.143 "Original Agreement" shall have the meaning given to such term in the recitals of this Agreement.
- **1.144** "Original Agreement Effective Date" shall have the meaning given to such term in the recitals of this Agreement.
- **1.145** "Original Agreement Term" means the period starting on the Original Agreement Effective Date and ending on the Restatement Effective Date.
- **1.146** "Party" or "Parties" shall have the meaning given to such term in the preamble to this Agreement.
- 1.147 "Party Materials" shall have the meaning given to such term in Section 2.7.1.
- "Patent Challenge" means any direct or indirect dispute or challenge, or any knowing, willful or reckless assistance in 1.148 the dispute or challenge, of the validity, patentability, scope, priority, construction, non-infringement, inventorship, ownership or enforceability of any Patent Right (a "Challenged Patent Right") licensed by a Party (the "Licensor") to the other Party (the "Licensee") under this Agreement or any claim thereof, or opposition or assistance in the opposition of the grant of any letters patent within the Challenged Patent Rights, in any legal or administrative proceedings, including in a court of law, before the United States Patent and Trademark Office or other agency or tribunal in any jurisdiction, or in arbitration including by reexamination, inter partes review, opposition, interference, post-grant review, nullity proceeding, preissuance submission, third party submission, derivation proceeding or declaratory judgment action; provided, however, that the term Patent Challenge shall not include (a) the Licensee or any of its Affiliates or sublicensees being an essential party in any patent interference proceeding before the United States Patent and Trademark Office, which interference the Licensee or its applicable Affiliate or sublicensee acts in good faith to try to settle or (b) the Licensee or any of its Affiliates or sublicensees, due to its status as an exclusive licensee of patent rights other than the Challenged Patent Rights, being named by the Licensor of such patent rights as a real party in interest in such an interference, so long as the Licensee or its applicable Affiliate or sublicensee either abstains from participation in, or acts in good faith to settle, the interference. For clarity, a Patent Challenge shall not include arguments made by the Licensee that (x) distinguish the inventions claimed in Patent Rights owned or controlled by the Licensee from those claimed in the Challenged Patent Rights but (y) do

not disparage the Challenged Patent Rights or raise any issue of Challenged Patent Rights' compliance with or sufficiency under applicable patent laws, regulations or administrative rules, in each case (i) in the ordinary course of ex parte prosecution of the Patent Rights owned or controlled by the Licensee or (ii) in *inter partes* proceedings before the United States Patent and Trademark Office or other agency or tribunal in any jurisdiction (excluding interferences or derivation proceedings), or in arbitration, wherein the Patent Rights owned or controlled by the Licensee have been challenged. For further clarity, unless in conflict with the definition of a "Patent Challenge" that exists as of the Restatement Effective Date under a Third Party Agreement applicable to the Challenged Patent Rights, a Patent Challenge shall not include any counterclaim made, filed or maintained by the Licensee or its applicable Affiliate or sublicensee as a defendant in any claim, demand, lawsuit, cause of action or other action made, filed or maintained by the Licensor or its Affiliate or designee asserting infringement of any Patent Right.

- 1.149 "Patent Rights" shall mean (a) all patents and patent applications in any country or supranational jurisdiction in the Territory, (b) any substitutions, divisionals, continuations, continuations-in-part, provisional applications, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like of any such patents or patent applications, (c) foreign counterparts of any of the foregoing, (d) all applications claiming priority to any of the foregoing, (e) any patents issuing on any patent application identified in clauses (a) through (d), (f) any application to which any of the foregoing claim priority and (g) any application that claims common priority with any of the foregoing.
- **1.150** "PCSK9" shall have the meaning given to such term in <u>Section 1.125</u>.
- 1.151____"Permitted Uses" shall have the meaning given to such term in Section 2.7.2.
- 1.152 "Person" shall mean an individual, Governmental Authority, government official, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, or any other form of entity not specifically listed herein.
- 1.153____"Pharmacovigilance Agreement" shall have the meaning given to such term in Section 3.11.1.
- **1.154** "**Phase I Clinical Trial**" shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(a).
- **1.155 "Phase II Clinical Trial"** shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b).
- **1.156** "**Phase III Clinical Trial**" shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(c).
- 1.157____"Phase IV Clinical Trial" shall mean (i) any human clinical trial (other than a Phase I Clinical Trial, Phase II Clinical Trial or Phase III Clinical Trial) in any country which is conducted on a Product for an Indication in the Field after Marketing Authorization of such

Product has been obtained from an appropriate Regulatory Authority in such country for such Indication, and includes (a) clinical trials conducted voluntarily after Marketing Authorization for enhancing marketing or scientific knowledge of an approved Indication in the Field or (b) trials conducted after Marketing Authorization due to request or requirement of a Regulatory Authority or as a condition of a previously granted Marketing Authorization or (ii) any REMS/RMP related study of a Product for an Indication in the Field after Marketing Authorization of such Product has been obtained from an appropriate Regulatory Authority in such country for such Indication.

- **1.158** "Post-Approval Shared Development Costs" shall mean, on a Collaboration Product-by-Collaboration Product basis, the sum of [**].
- **1.159** "Post-Approval Shared Regulatory Costs" shall mean, on an Collaboration Product-by-Collaboration Product basis, the sum of [**].
- 1.160____"Post-Termination Licensed Technology" shall have the meaning given to such term in Section 14.6.2(b).
- 1.161 "Pricing Approval" means, with respect to a product in any country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, (a) receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be) for such product in such country and (b) the earlier to occur of (i) Verve, its Affiliate or sublicensee indicating agreement with such price(s) in such country or (ii) Verve, its Affiliate or sublicensee commencing Commercialization activities for such Product in such country after Marketing Authorization (other than Pricing Approval).
- **1.162** "**Product**" shall mean any (a) Base Editor Product [**] or (b) Nuclease Product, as applicable.
- 1.163____"Receiving Party" shall have the meaning given to such term in Section 10.1.
- 1.164____"Reconciliation Report" shall have the meaning given to such term in Section 9.5.2(d).
- **1.165**_____"Regulatory Authority" shall mean any applicable Governmental Authority involved in granting approvals for the manufacturing or marketing of a Product (including Marketing Authorizations therefor) in the Territory, including in the United States, the FDA, and in the European Union, the EMA.
- 1.166____"Regulatory Documentation" shall have the meaning given to such term in Section 6.2.
- **1.167**_____"Research Plan" shall have the meaning given to such term in <u>Section 4.2</u>.
- **1.168** "Research Working Group" shall have the meaning given to such term in Section 3.4.1.
- **1.169** "Restatement Effective Date" shall have the meaning given to such term in the preamble to this Agreement.

1.170____"Royalty Term" shall mean:

- 1.170.1 on a country-by-country and Licensed Product-by-Licensed Product basis, the period during which royalties shall be paid on the sum of Net Sales of such Licensed Product in such country, from the First Commercial Sale of such Licensed Product until the latest of: (a) the expiration date of the last to expire Valid Claim within the Beam Base Editor Patent Rights, Beam C2C1 Patent Rights, Beam Collaboration Patent Rights, Verve Royalty-Bearing Patent Rights or Joint Collaboration Patent Rights Covering the applicable Licensed Product (or if the last such Valid Claim with respect to such Licensed Product in such country is a pending Valid Claim, the date such pending Valid Claim ceases to be a Valid Claim; provided, however, that subsequent issuance of such Valid Claim shall again extend the Royalty Term from the date of such issuance to the expiration date of such Valid Claim); (b) the period of regulatory exclusivity associated with such Licensed Product in such country; or (c) ten (10) years after the First Commercial Sale of such Licensed Product in such country, provided that, on a country-by-country basis, if the Royalty Term is only in effect in a given country for a given Licensed Product as a result of the applicable Licensed Product [**];
- 1.170.2 on a country-by-country and GalNAc Product-by-GalNAc Product basis, the period during which royalties shall be paid on the sum of Net Sales of such GalNAc Product in such country, from the First Commercial Sale of such GalNAc Product until the latest of: (a) the expiration date of the last to expire Valid Claim within the Verve GalNAc Patent Rights Covering the applicable GalNAc Product (or if the last such Valid Claim with respect to such GalNAc Product in such country is a pending Valid Claim, the date such pending Valid Claim ceases to be a Valid Claim; provided, however, that subsequent issuance of such Valid Claim shall again extend the Royalty Term from the date of such issuance to the expiration date of such Valid Claim); (b) the period of regulatory exclusivity associated with such GalNAc Product in such country; or (c) ten (10) years after the First Commercial Sale of such GalNAc Product in such country; or
- 1.170.3 on a country-by-country and Terminated Reversion Product-by-Terminated Reversion Product basis, the period during which royalties shall be paid on the sum of Net Sales of such Terminated Reversion Product in such country, from the First Commercial Sale of such Terminated Reversion Product until the latest of: (a) the expiration date of the last to expire Valid Claim within the Patent Rights within the Post-Termination Licensed Technology Covering the applicable Terminated Reversion Product (or if the last such Valid Claim with respect to such Terminated Reversion Product in such country is a pending Valid Claim, the date such pending Valid Claim ceases to be a Valid Claim; provided, however, that subsequent issuance of such Valid Claim shall again extend the Royalty Term from the date of such issuance to the expiration date of such Valid Claim); (b) the period of regulatory exclusivity associated with such Terminated Reversion

Product in such country; or (c) ten (10) years after the First Commercial Sale of such Terminated Reversion Product in such country.

- **1.171** "Safety Issue" shall mean, with respect to a Product, [**].
- **1.172** "Sales and Marketing Expenses" shall mean the sum of [**].
- 1.173____ "Senior Officers" shall have the meaning given to such term in Section 3.3.3.
- **1.174** "Shared Commercialization Costs" shall mean, with respect to a Collaboration Product, the sum of the following: [**].
- 1.175 "Shared Costs" shall mean any Shared Commercialization Costs or Shared Development Costs.
- **1.176** "Shared Development Costs" shall mean, with respect to a Collaboration Product, the sum of [**].
- **1.177** "Shared Distribution Costs" shall mean the sum of [**].
- **1.178** "Subcommittees" shall mean the JDC, JCC or any other committee or subcommittee (other than the JSC) formed in accordance with this Agreement.
- 1.179 "Sublicense Income" means all consideration (including upfront fees, annual or maintenance license fees, development, regulatory or sales milestones (net of any amount due to Beam under Section 9.2 or Section 9.3 for the identical or substantially the same milestone event)), received by Verve or its Affiliates from a Third Party under an agreement that includes the grant of any sublicense of the rights granted to Verve under Section 2.1.1 for [**] or [**] Base Editor Products, but excluding (a) royalties on Net Sales (or other payments, such as profit sharing payments, calculated as a percentage of net sales less deductions, provided that royalty payments under Section 9.4.1 for such products are paid), (b) [**] for [**] or [**] Base Editor Products.
- 1.180____ "Subsequent Development Plan" shall have the meaning given to such term in Section 4.3.2(a).
- 1.181____ "Target Nomination Notice" shall have the meaning given to such term in Section 2.5.2.
- **1.182**____"Term" shall have the meaning given to such term in <u>Section 14.1</u>.
- **1.183** "**Terminated Target**" means each of [**].
- **1.184** "Terminated Target Product" shall mean any Base Editor Product [**] of a Terminated Target, and targets such Base Editor to such sequence.
- 1.185_____ "Terminated Reversion Product" shall have the meaning given to such term in Section 14.6.2(a).

- **1.186** "Territory" shall mean all of the countries in the world, and their territories and possessions.
- **1.187** "Third Party" shall mean a Person other than Verve, Beam or their respective Affiliates.
- 1.188 "Third Party Agreements" shall mean (a) subject to Section 3.3.3(b)(viii), any agreement entered into after the Restatement Effective Date between a Third Party and Verve or its Affiliate pursuant to which Verve or its Affiliate gains rights to use such Third Party's intellectual property in the Development, Manufacture or Commercialization of a Licensed Product or Collaboration Product under this Agreement, (b) with respect to Beam, any agreement set forth on Schedule 1.188(a) and, with respect to Verve, any agreement set forth on Schedule 1.188(b) or (c) any agreement between a Third Party and a Party or its Affiliate that is deemed a "Third Party Agreement" under Section 2.4.3.
- **1.189____**"Third Party Payments" shall mean compensation paid to any Third Party by a Party or by both Parties (or their respective Affiliates) under any Third Party Agreement and, contingent and effective upon the effective date of the [**], compensation paid to [**] or [**] under the [**] Agreement with respect to the applicable Collaboration Product.
- **1.190** "[**]" shall mean the [**].
- 1.191 "[**] **Product**" shall mean any Base Editor Product [**] and targets such Base Editor to such sequence, in any formulation and dosage form (including any formulations with [**], with and without GalNAc). For clarity, a [**] Product may also be a GalNAc Product.
- 1.192____"[**] **Product Competitive Infringement**" shall have the meaning given to such term in <u>Section 12.5</u>.
- 1.193 "[**] **Product-Specific Know-How**" means any Verve [**] Know-How that [**].
- 1.194____"[**] Product-Specific Patent Right" means (a) each Verve [**] Patent Right that solely claims [**] Product-Specific Know-How as listed on Schedule 1.194 and (b) any Verve [**] Patent Right that solely claims [**] Product-Specific Know-How and that is filed by Verve within [**] of the Restatement Effective Date.
- Patent Rights that has not been (i) held permanently revoked, unenforceable, unpatentable or invalid by a decision of a court or governmental body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, (ii) rendered unenforceable through disclaimer, or (iii) permanently lost through an interference or opposition proceeding without any right of appeal or review, or not appealed or put in for review within the applicable statutory or regulatory period; or (b) a pending claim of a pending patent application within such Patent Rights that has not been (i) abandoned or finally rejected without the possibility of appeal or refiling or (ii) pending more than [**] from the date of the first substantive office action on such pending patent application, provided such patent application is not pending more than [**] from its earliest priority date. A pending claim that ceases to be a Valid Claim due to the foregoing time

- limit shall, if it later issues, qualify again as a Valid Claim, provided that it meets the requirements of clauses (a)(i)-(iii) of the foregoing definition.
- **1.196** "Verve" shall have the meaning given to such term in the preamble to this Agreement.
- 1.198_____"Verve Base Editing Technology" shall mean (a) (i) all Know-How, patentable or otherwise and Patent Rights

 Controlled by Verve or its Affiliates as of the Restatement Effective Date and that Covers [**] and (ii) Patent Rights

 Controlled by Verve or its Affiliates during the Term and that Cover the [**], and (b) (i) all Verve Collaboration

 Technology and (ii) Verve's interest in the Joint Collaboration Technology, in each case ((i) and (ii)), (A) that Covers the

 [**].
- **1.200** "Verve Collaboration Patent Rights" shall mean Patent Rights which (a) as of the Restatement Effective Date or during the Term are Controlled by Verve or its Affiliates and (b) claim Verve Collaboration Know-How.
- **1.201** "Verve Collaboration Technology" shall mean Verve Collaboration Know-How and Verve Collaboration Patent Rights.
- 1.202 "Verve Competitive Product" shall have the meaning given to such term in <u>Section 1.203</u>.
- 1.203 "Verve Competitive Program" shall mean any research or development program for which [**], with the goal of discovering or developing (a) a Base Editor Product [**] and targets such Base Editor to such sequence or (b) a Nuclease Product (such product ((a) or (b)), an "Verve Competitive Product"); provided that, the determination as to whether a Third Party is engaged in a Verve Competitive Program shall be conclusively determined based on [**].
- **1.204** "Verve GalNAc Know-How" shall mean all Know-How, patentable or otherwise, which (a) is Controlled by Verve or its Affiliates as of the Restatement Effective Date, and (b) [**].
- **1.205** "Verve GalNAc Patent Rights" shall mean Patent Rights which (a) are Controlled by Verve or its Affiliates as of the Restatement Effective Date and (b) claim Verve GalNAc Know-How. [**].
- 1.206 "Verve GalNAc Technology" shall mean Verve GalNAc Know-How and Verve GalNAc Patent Rights.

- 1.207 "Verve Indemnified Parties" shall have the meaning given to such term in Section 13.1.
- 1.208____"Verve IP Infringement" shall have the meaning given to such term in Section 12.6.1.
- **1.209**____"Verve Lipid Know-How" shall mean all Know-How, patentable or otherwise, which (a) is Controlled by Verve or its Affiliates as of the Restatement Effective Date, and (b) [**].
- **1.210____"Verve Lipid Patent Rights"** shall mean Patent Rights which (a) as of the Restatement Effective Date are Controlled by Verve or its Affiliates and (b) claim [**] or otherwise claim Verve Lipid Know-How. As of the Restatement Effective Date, Verve Lipid Patent Rights are listed on <u>Schedule 1.210</u>.
- **1.211** "Verve Lipid Technology" shall mean Verve Lipid Know-How and Verve Lipid Patent Rights. For clarity, the Parties acknowledge that Verve Lipid Technology shall not include any Know-How or Patent Rights licensed to Verve from [**].
- **1.212** "Verve [**] Technology" shall mean any Patent Right and Know-How Controlled by Verve or its Affiliates as of the Restatement Effective Date that (i) covers or claims [**] and (ii) [**].
- **1.213**____"Verve-[**] Agreement" shall mean the License Agreement by and between [**] and Verve dated as of [**], as such agreement may be amended from time to time in accordance with its terms.
- 1.214____"Verve Opt-Out Date" shall have the meaning given to such term in Section 5.4.
- 1.215____"Verve Opt-Out Option" shall have the meaning given to such term in <u>Section 5.4</u>.
- 1.216____"Verve Product Competitive Infringement" shall have the meaning given to such term in Section 12.3.1.
- 1.217____"Verve Product Specific Competitive Infringement" shall have the meaning given to such term in Section 12.4.1.
- 1.218____"Verve Product-Specific Know-How" means any (a) [**] and (b) [**].
- **1.219**______ "Verve Product-Specific Patent Right" means any Beam Base Editor Patent Right, Beam C2C1 Patent Right, or Beam Collaboration Patent Right solely as to claims in any patent or patent application that specifically and solely claim any Verve Product-Specific Know-How.
- 1.220 "Verve Royalty-Bearing Know-How" means all Know-How within the Verve Base Editing Technology (a) in existence as of the Restatement Effective Date; or (b) conceived, developed, generated or reduced to practice during the Term (i) solely by Verve, its respective Affiliates or other persons acting on behalf of Verve or (ii) jointly by, on the one hand, Beam, its Affiliates or persons acting on behalf of Beam and, on the other hand, Verve, its Affiliates or persons acting on behalf of Verve, in each case of clauses (i) and (ii), through modifying a Base Editor Covered by a Beam Base Editor Patent Right.

- **1.221**____"Verve Royalty-Bearing Patent Rights" means Patent Rights which (a) are Controlled by Verve or its Affiliates as of the Restatement Effective Date or during the Term and (b) claim Verve Royalty-Bearing Know-How.
- 1.222 "Verve Surviving Sublicensee" shall have the meaning given to such term in Section 2.2.4.
- 1.223_____ "Verve Surviving Sublicensee" shall have the meaning given to such term in Section 2.2.4.
- 1.224____"Verve Terminated Product" shall have the meaning given to such term in Section 14.6.1.
- 1.225 "Verve Third Party Agreement" shall have the meaning given to such term in Section 11.2.12.
- **1.226**____"Verve [**] Know-How" shall mean all Know-How, patentable or otherwise, which (a) is Controlled by Verve or its Affiliates as of the Restatement Effective Date and (b) is necessary or useful for the Development, Commercialization or Manufacture of a [**] Product.
- 1.227____"Verve [**] Patent Rights" shall mean Patent Rights which (a) as of the Restatement Effective Date are Controlled by Verve or its Affiliates and (b) claim Verve [**] Know-How. Verve [**] Patent Rights include those Patent Rights listed on Schedule 1.227.
- 1.228____"Verve [**] Technology" shall mean Verve [**] Know-How and Verve [**] Patent Rights.
- 1.229____"Verve [**] Technology Transfer" shall have the meaning given to such term in Section 2.6.1.
- **1.230____"Verve-[**] Agreement**" shall mean the [**] License Agreement by and between [**] and Verve, dated as of [**], as such agreement may be amended from time to time in accordance with its terms.
- 1.231 "[**]" shall have the meaning given to such term in <u>Schedule 1.231</u>.

Article 2 LICENSES

- 2.1 License Grants; Retained Rights.
 - **Licensed Products**. Subject to the terms and conditions of this Agreement (including Section 2.4.1), Beam hereby grants, and shall cause its Affiliates to grant, to Verve an exclusive (even as to Beam and its Affiliates, except as set forth in Section 2.1.10) license under the Beam Base Editor Technology, Beam C2C1 Technology, and Beam's interest in the Joint Collaboration Technology, with a right to grant and authorize the further grant through multiple tiers of sublicenses in accordance with this Agreement (including Section 2.2), solely to

Develop, make, have made, use, offer for sale, sell, have sold, and import Licensed Products in the Field in the Territory.

- [**] Products. Subject to the terms and conditions of this Agreement (including Section 2.4.1), Verve hereby grants, and shall cause its Affiliates to grant, to Beam an exclusive (even as to Verve and its Affiliates), royalty-free, fully paid-up (except as to payments due to [**] under the Verve-[**] Agreement in accordance with Section 2.4.5) license under the Verve [**] Technology, the Verve GalNAc Technology and the Verve [**] Technology (to the extent of Verve's rights to any such Verve [**] Technology that is licensed to Verve pursuant to the Verve-[**] Agreement), with a right to grant and authorize the further grant through multiple tiers of sublicenses in accordance with this Agreement (including Section 2.2), solely to Develop, make, have made, use, offer for sale, sell, have sold, and import [**] Products in the Field in the Territory. Notwithstanding anything to the contrary in this Agreement, the sublicense granted in this Section 2.1.2 under Patent Rights within the Verve [**] Technology licensed to Verve pursuant to the Verve-[**] Agreement shall be non-exclusive.
- **2.1.3 Verve GalNAc Technology Research License**. Subject to the terms and conditions of this Agreement, Verve hereby grants, and shall cause its Affiliates to grant, to Beam a non-exclusive, royalty-free, fully paid-up license (with no right to sublicense) solely to perform research and pre-clinical development activities under the Verve GalNAc Technology.
- **Yerve GalNAc Technology Exploitation License.** Subject to the terms and conditions of this Agreement, on a Licensed GalNAc Target-by-Licensed GalNAc Target basis, Verve hereby grants, and shall cause its Affiliates to grant, to Beam a non-exclusive and royalty-bearing license under the Verve GalNAc Technology, with a right to grant and authorize the further grant through multiple tiers of sublicenses in accordance with this Agreement (including Section 2.2), solely to Develop, make, have made, use, offer for sale, sell, have sold, and import Base Editor Products for the applicable Licensed GalNAc Target in the Field in the Territory.
- 2.1.5 <u>Verve Lipid Technology</u>. Subject to the terms and conditions of this Agreement, Verve hereby grants, and shall cause its Affiliates to grant, to Beam an exclusive (even as to Verve and its Affiliates), royalty-free, fully paid-up license under the Verve Lipid Technology, with a right to grant and authorize the further grant through multiple tiers of sublicenses in accordance with this Agreement (including <u>Section 2.2</u>), solely to Develop, make, have made, use, offer for sale, sell, have sold, and import Base Editor Products in the Field in the Territory, other than Base Editor Products directed towards Licensed Targets, provided, for clarity, that this exception shall cease to apply, on a target-by-target basis, upon termination of the licenses granted to Verve pursuant to Section 2.1.1 in relation to Licensed Products directed to the applicable target.

- 2.1.6 Collaboration Product Research and Development License. Subject to the terms and conditions of this Agreement, on a Collaboration Product-by-Collaboration Product basis, effective upon Beam's exercise of the Beam Opt-In Option with respect to the applicable Collaboration Product, Verve hereby grants, and shall cause its Affiliates to grant, to Beam a non-exclusive license under the Know-How (patentable or otherwise) and Patent Rights Controlled by Verve or its Affiliates as of the Restatement Effective Date or during the Term, and Verve's interest in the Joint Collaboration Technology, with a right to grant and authorize the further grant through multiple tiers of sublicenses in accordance with this Agreement (including Section 2.2), solely to conduct the activities allocated to Beam under a Research Plan or Development Plan for such Collaboration Product (if any).
- 2.1.7 Collaboration Product Commercialization License. Subject to the terms and conditions of this Agreement, on a Collaboration Product-by-Collaboration Product basis, effective upon Beam's exercise of the Beam Opt-In Option with respect to a Collaboration Product, Verve hereby grants, and shall cause its Affiliates to grant, to Beam a non-exclusive license under the Know-How (patentable or otherwise) and Patent Rights Controlled by Verve or its Affiliates as of the date of Beam's exercise of the Beam Opt-In Option or thereafter during the Term, and Verve's interest in the Joint Collaboration Technology, with a right to grant and authorize the further grant of sublicenses as permitted under this Agreement (including the Commercialization Plan) or the Co-Promotion Agreement, to offer for sale, sell, have sold, and import (including Commercialize and Co-Promote) such Collaboration Product in the Field in the Collaboration Territory.
- **Yerve Base Editing Technology**. Subject to the terms and conditions of this Agreement, Verve hereby grants, and shall cause its Affiliates to grant, to Beam a worldwide, exclusive (even as to Verve and its Affiliates), royalty-free, fully paid-up, perpetual, irrevocable, license under the Verve Base Editing Technology, with a right to grant and authorize the further grant through multiple tiers of sublicenses in accordance with this Agreement (including Section 2.2), solely to Develop, make, have made, use, offer for sale, sell, have sold, and import Base Editor Products for all fields and uses, excluding Base Editor Products directed towards Licensed Targets, provided, for clarity, that this exception shall cease to apply, on a target-by-target basis, upon termination of the licenses granted to Verve pursuant to Section 2.1.1 in relation to Licensed Products directed to the applicable target.
- **2.1.9** GalNAc Grant Back License. Subject to the terms and conditions of this Agreement, Beam hereby grants, and shall cause its Affiliates to grant, to Verve a non-exclusive, worldwide, royalty-free, fully paid-up, perpetual, irrevocable license (with the right to grant and authorize the further grant through multiple tiers of sublicenses in connection with a product Controlled by Verve) to Develop, make, have made, use, offer for sale, sell, have sold, and import products that comprise or include GalNAc (or any modification described below

in this <u>Section 2.1.9</u>) (including Base Editor Products directed towards Licensed Targets, but excluding all other Base Editor Products), under any Patent Rights filed by Beam to the extent of any claims that cover an invention conceived, developed, generated or reduced to practice by Beam in the [**] period following the Restatement Effective Date that constitutes a modification to any confidential GalNAc-LNP compositions, components or formulations, in each case to the extent disclosed to Beam by Verve.

Existing Licensed Product-by-Existing Licensed Product basis, Beam hereby grants, and shall cause its Affiliates to grant, to Verve a non-exclusive license under any Beam FTO Patent Rights, with a right to grant and authorize the further grant through multiple tiers of sublicenses in accordance with this Agreement (including Section 2.2), solely to Develop, make, have made, use, offer for sale, sell, have sold, and import the applicable Existing Licensed Product in the Field and Territory. "Existing Licensed Product" shall mean each of the Licensed Products directed towards Licensed Targets having the composition described in Schedule 2.1.10. "Beam FTO Patent Rights" shall mean, subject to Section 2.4.3(c), on an Existing Licensed Product-by-Existing Licensed Product basis, any [**].

2.1.11 Freedom to Operate Licenses from Verve.

- (a) Subject to the terms and conditions of this Agreement, on an Existing Licensed Product by Existing Licensed Product basis, Verve hereby grants, and shall cause its Affiliates to grant, to Beam a non-exclusive license under any Verve FTO Patent Rights, with a right to grant and authorize the further grant through multiple tiers of sublicenses in accordance with this Agreement (including Section 2.2), solely to Develop, make, have made, use, offer for sale, sell, have sold, and import the Existing [**] Product in the Field and Territory. "Existing [**] Product" shall mean the [**] Product having the composition described in Schedule 2.1.11. "Verve FTO Patent Rights" shall mean any Patent Rights Controlled by Verve or its Affiliates during the Term to the extent the claims therein Cover the composition or use of the Existing [**] Product, or the process or method used to manufacture the Existing [**] Product as of the Restatement Effective Date (but not to the extent Covering any other composition used, formulated or administered with such composition or any other manufacturing process or method), and would, but for the license granted pursuant to this Section 2.1.11, be infringed by the Existing [**] Product.
- (b) Subject to the terms and conditions of this Agreement, Verve hereby grants, and shall cause its Affiliates to grant, to Beam, a worldwide, non-exclusive, royalty-free, fully paid-up, perpetual, irrevocable, license, with a right to grant and authorize the further grant through multiple tiers of sublicenses in accordance with this Agreement (including Section 2.2),

under any Patent Rights Controlled by Verve that Cover the composition or use of, including any methods of manufacturing, [**] (provided, for clarity, that this exception shall cease to apply, on a target-by-target basis, upon termination of the licenses granted to Verve pursuant to Section 2.1.1 in relation to Licensed Products directed to the applicable target), provided that such Patent Rights are limited to Patent Rights claiming Know-How that was, on a Licensed Target-by-Licensed Target basis, invented solely by Verve or its Affiliates or other persons acting on behalf of Verve solely through the Development, Commercialization or Manufacture of Licensed Products during the period commencing on the Restatement Effective Date and ending on the later of (I) [**] and (II) [**].

- **Retained Rights**. Notwithstanding anything to the contrary in this Agreement, including without limitation the license grant to Verve set forth in Section 2.1.1, Beam and its Affiliates shall retain the right under Beam Base Editor Technology, Beam C2C1 Technology, and Beam's interest in the Joint Collaboration Technology to exercise their respective rights and perform their respective obligations under this Agreement, including without limitation the Development of Collaboration Products in the Territory as set forth in this Agreement (including any Development Plan) and the Commercialization of Collaboration Products in the Collaboration Territory as set forth in this Agreement (including the Commercialization Plan) or a Co-Promotion Agreement.
- 2.1.13 Assignment to Beam of [**] Product-Specific Patent Rights. Verve hereby assigns, transfers, conveys and delivers to Beam all of Verve's right, title and interest in, to and under the [**] Product-Specific Patent Rights. Verve shall, within [**] following the Restatement Effective Date, execute and deliver to Beam an assignment of the [**] Product-Specific Patent Rights in forms registrable or recordable in the United States Patent and Trademark Office or applicable foreign offices to the extent necessary to assign the [**] Product-Specific Patent Rights, all in forms reasonably acceptable to Beam, along with copies of all confirmatory assignments executed by the inventors of the [**] Product-Specific Patent Rights. The foregoing assignment includes the rights to prosecute, maintain and enforce the [**] Product-Specific Patent Rights in any and all countries of the world, provided that Beam shall direct its prosecution of claims within the [**] Product-Specific Patent Rights only to Base Editor Products [**] of [**] and targets the Base Editor in such Base Editor Product to such sequence. Notwithstanding anything to the contrary in this Agreement, the Patent Rights licensed by Beam to Verve under Section 2.1.1 include the [**] Product-Specific Patent Rights.
- **2.1.14** Assignment to Verve of [**] Patent Rights. Beam hereby assigns, transfers, conveys and delivers to Verve all of Beam's right, title and interest in, to and under the [**] Patent Rights. Beam shall, within [**] following the Restatement Effective Date, execute and deliver to Verve an assignment of the [**] Patent Rights in forms registrable or recordable in the United States Patent and

Trademark Office or applicable foreign offices to the extent necessary to assign the [**] Patent Rights, all in forms reasonably acceptable to Verve, along with copies of all confirmatory assignments executed by the inventors of the [**] Patent Rights. The foregoing assignment includes the rights to prosecute, maintain and enforce the [**] Patent Rights in any and all countries of the world, provided that Verve shall direct its prosecution of claims within the [**] Patent Rights only to Base Editor Products [**] and targets the Base Editor in such Base Editor Product to such sequence. Notwithstanding anything to the contrary in this Agreement, the Patent Rights licensed by Verve to Beam under Sections 2.1.2, 2.1.6, 2.1.7 and 2.1.8 include the [**] Patent Rights.

2.1.15 [**] **Agreement**. Subject to the terms of this <u>Section 2.1.15</u>, the Parties agree and acknowledge that the licenses granted by Verve to Beam under this Agreement as of the Restatement Effective Date do not include any Know-How or Patent Rights [**]. On a Collaboration Product-by-Collaboration Product basis, Beam may elect in writing, in conjunction with its exercise of the applicable Beam Opt-In Option, to include in the licenses granted by Verve to Beam under this Agreement, any such Know-How or Patent Rights that is(are) [**], in a reasonable form to be mutually agreed upon by the Parties in writing. This <u>Section 2.1.15</u> does not limit Verve's obligations in Section 11.5.2.

2.2 Sublicenses.

- 2.2.1 In no event shall any sublicense granted pursuant to Section 2.1 diminish, reduce or eliminate any of the obligations of the sublicensing Party under this Agreement. Any sublicense granted pursuant to Section 2.1 shall be subject and subordinate to, and consistent with, the terms and conditions of this Agreement and shall require each such sublicensee to comply with all applicable terms of this Agreement, including the prohibition of further sublicensing by the sublicensee except where such sublicense is in compliance with the provisions of this Agreement.
- [**]. The sublicensing Party shall provide the other Party with a fully-executed copy of any agreement (which the sublicensing Party may redact as necessary to protect confidential or commercially sensitive information) reflecting any such sublicense promptly after the execution thereof, excluding sublicenses granted by a Party, solely for purposes of performing services on behalf of such Party, to a Third Party that is principally engaged in the performance of contract research, development or manufacturing services. If a Party grants a sublicense, the terms and conditions of this Agreement and the Third Party Agreements that are applicable to sublicensees shall apply to such sublicensee to the same extent as they apply to such Party. Further, the sublicensing Party assumes full responsibility, and shall remain primarily liable, for causing the performance of all obligations of each Affiliate and sublicensee of such sublicensing Party to which it grants a sublicense, and will itself pay and account to the other Party for all payments due under this Agreement by reason of operation of any such sublicense.

2.2.3 [**].

- Any sublicensed rights granted by Verve pursuant to Section 2.2.2 with respect to a Verve Terminated Product 2.2.4 shall terminate effective upon the termination of this Agreement with respect to such Verve Terminated Product, provided that, subject to and to the extent permitted under the Third Party Agreements, the terms of such sublicensed rights shall not terminate if, as of the effective date of such termination, the relevant sublicensee for such sublicense is not in material breach of its obligations to Verve under its sublicense agreement, and within [**] of such termination, such sublicensee agrees in writing to be bound directly to Beam under a license agreement substantially similar to this Agreement with respect to the rights sublicensed and granted hereunder, substituting such sublicensee (a "Verve Surviving Sublicensee") for Verve, and provided further that (a) the scope of the rights granted to the Verve Surviving Sublicensee under such license agreement (with respect to such Verve Terminated Product) shall be equal to (or, upon mutual agreement of the Parties, less than) the scope of the rights that had been sublicensed and granted by Verve to the Verve Surviving Sublicensee pursuant to such sublicense agreement; (b) such license agreement shall obligate the Verve Surviving Sublicensee to pay directly to Beam amounts corresponding to those set forth in Article 9 which are payable based on the activities of such Verve Surviving Sublicensee, its Affiliates and its sublicensees from and after the effective date of such termination; (c) Beam will not be required to undertake obligations in addition to those required by this Agreement; (d) Beam's rights under such direct license will be consistent with its rights under this Agreement, taking into account the scope of the license granted under such direct license; and (e) such license agreement shall not modify the rights and obligations of the Parties following any termination of this Agreement in whole or in part.
- 2.2.5 Any sublicensed rights granted by Beam pursuant to Section 2.2.2 with respect to a Beam Terminated Product shall terminate effective upon the termination of this Agreement with respect to such Beam Terminated Product, provided that, subject to and to the extent permitted under the Third Party Agreements, the terms of such sublicensed rights shall not terminate if, as of the effective date of such termination, the relevant sublicensee for such sublicense is not in material breach of its obligations to Beam under its sublicense agreement, and within [**] of such termination, such sublicensee agrees in writing to be bound directly to Verve under a license agreement substantially similar to this Agreement with respect to the rights sublicensed and granted hereunder, substituting such sublicensee (a "Beam Surviving Sublicensee") for Beam, and provided further that (a) the scope of the rights granted to the Beam Surviving Sublicensee under such license agreement (with respect to such Beam Terminated Product) shall be equal to (or, upon mutual agreement of the Parties, less than) the scope of the rights that had been sublicensed and granted by Beam to the Surviving Sublicensee pursuant to such sublicense agreement; (b) such license agreement shall obligate the Beam Surviving Sublicensee to pay directly to Verve amounts corresponding to those set forth in Article 9 which are payable based on the activities of such Beam Surviving Sublicensee, its Affiliates and its sublicensees from and after the

effective date of such termination; (c) Verve will not be required to undertake obligations in addition to those required by this Agreement; (d) Verve's rights under such direct license will be consistent with its rights under this Agreement, taking into account the scope of the license granted under such direct license; and (e) such license agreement shall not modify the rights and obligations of the Parties following any termination of this Agreement in whole or in part.

2.2.6 The Parties acknowledge and agree that:

- (a) [**] is an intended third party beneficiary of the rights granted to Verve by Beam pursuant to Section 2.1.1 under the Beam Base Editor Technology and Beam C2C1 Technology licensed to Beam by [**] under the Beam-[**] Agreement, solely for the purpose of enforcing all patent challenge, intellectual property ownership, indemnification and insurance and compliance with law provisions applicable to such Beam Base Editor Technology and Beam C2C1 Technology licensed to Verve under this Agreement and, with respect to such insurance and indemnification provisions, each applicable Product, and enforcing the right to terminate this Agreement for breach of such patent challenge, indemnification (solely with respect to Verve's obligation to indemnify [**] as set forth in Schedule 2.4.1(a)) and insurance provisions;
- (b) Each other Institution is an intended third party beneficiary of the rights granted to Verve by Beam pursuant to Section 2.1.1 under the Beam Base Editor Technology and Beam C2C1 Technology licensed to Beam by such other Institution under the applicable Third Party Agreement for the purpose of enforcing such Institution's rights, including indemnification and insurance provisions that relate to such Beam Base Editor Technology and Beam C2C1 Technology licensed to Verve under this Agreement, and each Product relating to such grant of rights;
- (c) The rights of [**] or any other Institution may be enforced by any Institution in any court of competent jurisdiction and, without limiting the generality of the foregoing, Verve consents to jurisdiction in Massachusetts courts with respect to any such Institution's enforcement of its rights under this Agreement; and
- (d) Notwithstanding the governing law selected under this Agreement, Verve agrees that, in the event of any difference in interpretation or result as between the laws of the jurisdiction of this Agreement and the laws of Massachusetts, the laws of Massachusetts shall control in any action in which [**] or any other Institution is enforcing its rights under this Agreement.

2.3 Other IP.

- 2.3.1 Subject to the terms and conditions of this Agreement, Beam hereby grants to Verve the non-exclusive right, free of charge, to use the Beam name and logo solely for the purpose of Co-Promoting the Collaboration Products in accordance with the terms of this Agreement and the Co-Promotion Agreement, and Verve hereby grants to Beam the non-exclusive right, free of charge, to use the Verve name and logo in the Collaboration Territory solely for the purpose of Co-Promoting the Collaboration Products in accordance with the terms of this Agreement and the Co-Promotion Agreement, provided that such rights shall be exercised, and all Collaboration Products bearing such names or logos shall be manufactured, in accordance with the quality standards established by the JSC. Beam or its Affiliate shall remain the owner of the Beam name and logo and the trademarks and the goodwill pertaining thereto. Verve or its Affiliate shall remain the owner of the Verve name and logo and the trademarks and the goodwill pertaining thereto. Notwithstanding any provision of this Agreement or any Co-Promotion Agreement to the contrary, the quality standards established by the JSC may not conflict with or otherwise contravene any quality standards or restrictions on use set forth in the Co-Promotion Agreement.
- 2.3.2 Subject to the terms and conditions of this Agreement, Verve hereby grants to Beam an exclusive (except as to Verve and its Affiliates) license, free of charge, to use the Collaboration Marks solely in connection with Co-Promoting the Collaboration Products in the Collaboration Territory in accordance with the terms of this Agreement and the Co-Promotion Agreement.
- 2.3.3 Subject to the terms and conditions of this Agreement, each Party hereby grants to the other Party an exclusive (except as to such Party and its Affiliates) license, free of charge, to use the copyrighted material created for use in connection with the marketing of the Collaboration Products in the Collaboration Territory solely for use in connection with Co-Promoting the Collaboration Products in the Collaboration Territory in accordance with the terms of this Agreement and the Co-Promotion Agreement.

2.4 Third Party Agreements.

Notwithstanding anything to the contrary in this Agreement, each Party acknowledges and agrees that the rights, licenses, and sublicenses granted by the other Party to such Party in this Agreement (including any right to sublicense) are subject to the terms of the Third Party Agreements set forth on Schedule 1.188(a) (with respect to rights granted by Beam) and Schedule 1.188(b) (with respect to rights granted by Verve) and the rights granted to Third Parties thereunder, the scope of the licenses granted to such other Party thereunder and the rights retained by such Third Parties and any other Third Parties (including Governmental Authorities) set forth therein, including, with respect to Beam Third Party Agreements, (a) Sections [**] of the Beam-[**] Agreement, (b) Sections [**] of the Beam-[**] Agreement, (c) Sections [**] of the Beam-[**] Agreements, (x) Sections [**] of the Verve-[**] Agreement and (z) in relation to

Collaboration Products only, Sections [**] of the Verve-[**] License Agreement. Without limiting the above in any way, at the granting Party's request, the receiving Party shall use Commercially Reasonable Efforts to, and cause its Affiliates and all sublicensees to use Commercially Reasonable Efforts to, take such reasonable actions, as may be required to assist the granting Party in complying with its obligations under Third Party Agreements, solely to the extent applicable to such receiving Party's rights or obligations under this Agreement. Without limiting any of the foregoing, (a) Verve agrees to be bound by the terms and conditions of the provisions set forth in Schedule 2.4.1(a), as applicable, with respect to sublicenses granted by Beam to Verve under Section 2.1 under Third Party Agreements, and (b) Beam agrees to be bound by the terms and conditions of the provisions set forth in Schedule 2.4.1(b), as applicable, with respect to sublicenses granted by Verve to Beam under Section 2.1 under Third Party Agreements.

2.4.2 Verve acknowledges and agrees that, if any of the licenses granted to Beam under the Beam Third Party Agreements are terminated, in whole or in part, then, to the extent that any Patent Rights or Know-How licensed under such terminated license is part of Beam Base Editor Technology hereunder, then Verve's license under such terminated licenses(s) shall automatically terminate, subject to any right of Verve to receive a direct license from the relevant Third Party, including from [**] under Section [**] of the Beam-[**] Agreement, Section [**] Agreement, and Section [**] of the Beam-[**] Agreement. Beam acknowledges and agrees that, if any of the licenses granted to Verve under the Verve Third Party Agreements are terminated, in whole or in part, then, to the extent that any Patent Rights or Know-How licensed under such terminated license is part of Verve Lipid Technology, Verve [**] Technology, Verve GalNAc Technology or Verve [**] Technology hereunder, then Beam's license under such terminated licenses(s) shall automatically terminate, subject to any right of Beam to receive a direct license from the relevant Third Party.

2.4.3 Intellectual property licensed or acquired after the Restatement Effective Date.

(a) Notwithstanding anything to the contrary in this Agreement, in the event that Beam enters into an agreement or arrangement following the Restatement Effective Date under which Beam or its Affiliate acquires Control (whether by license or acquisition) of any Patent Rights that would, [**] described below in this Section 2.4.3(a), be Beam Base Editor Patent Rights, such Patent Rights [**] Beam Base Editor Patent Rights [**] Verve makes [**]. To the extent permitted under any confidentiality obligations related to such arrangement or agreement, (i) [**]. Beam will use commercially reasonable efforts to secure the right to disclose to Verve the information described in the foregoing clauses (A) through (C). Beam shall be required to provide the notice described in clause (i) of this Section 2.4.3(a) within [**] of the effective date of the applicable

agreement or arrangement. If Verve does not provide the notice described in clause (iii) of this <u>Section 2.4.3(a)</u> or indicates in such written notice that it does not wish to obtain a sublicense under the relevant Patent Rights, such Patent Rights are hereby deemed not to be Beam Base Editor Patent Rights hereunder.

- (b) Notwithstanding anything to the contrary in this Agreement, in the event that Beam enters into an agreement or arrangement following the Restatement Effective Date under which Beam or its Affiliate acquires Control (whether by license or acquisition) of any Patent Rights that would, [**] described below in this Section 2.4.3(b), be Beam C2C1 Patent Rights, such Patent Rights [**] Beam C2C1 Patent Rights [**] Verve makes [**]. To the extent permitted under any confidentiality obligations related to such arrangement or agreement, (i) [**]. Beam will use commercially reasonable efforts to secure the right to disclose to Verve the information described in the foregoing clauses (A) through (C). Beam shall be required to provide the notice described in clause (i) of this Section 2.4.3(b) within [**] of the effective date of the applicable agreement or arrangement. If Verve does not provide the notice described in clause (iii) of this Section 2.4.3(b) or indicates in such written notice that it does not wish to obtain a sublicense under the relevant Patent Rights, such Patent Rights are hereby deemed not to be Beam C2C1 Patent Rights hereunder.
- (c) Notwithstanding anything to the contrary in this Agreement, in the event that Beam enters into an agreement or arrangement following the Restatement Effective Date under which Beam or its Affiliate acquires Control (whether by license or acquisition) of any Patent Rights that would, [**] described below in this Section 2.4.3(c), be Beam FTO Patent Rights, such Patent Rights [**] Beam FTO Patent Rights [**] Verve makes [**]. To the extent permitted under any confidentiality obligations related to such arrangement or agreement, (i) [**]. Beam will use commercially reasonable efforts to secure the right to disclose to Verve the information described in the foregoing clauses (A) through (C). Beam shall be required to provide the notice described in clause (i) of this Section 2.4.3(c) within [**] of the effective date of the applicable agreement or arrangement. If Verve does not provide the notice described in clause (iii) of this Section 2.4.3(c) or indicates in such written notice that it does not wish to obtain a sublicense under the relevant Patent Rights, such Patent Rights are hereby deemed not to be Beam FTO Patent Rights hereunder.
- (d) Notwithstanding anything to the contrary in this Agreement, in the event that Verve enters into an agreement or arrangement following the Restatement Effective Date under which Verve or its Affiliate acquires Control (whether by license or acquisition) of any Patent Rights that would, [**] described below in this Section 2.4.3(d), be Verve FTO

Patent Rights or Patent Rights within the Verve Base Editing Technology, as the case may be, such Patent Rights [**] Verve FTO Patent Rights or Patent Rights within the Verve Base Editing Technology, as the case may be, [**] Beam makes [**]. To the extent permitted under any confidentiality obligations related to such arrangement or agreement, (i) [**]. Verve will use commercially reasonable efforts to secure the right to disclose to Beam the information described in the foregoing clauses (A) through (C). Verve shall be required to provide the notice described in clause (i) of this Section 2.4.3(d) within [**] of the effective date of the applicable agreement or arrangement. If Beam does not provide the notice described in clause (iii) of this Section 2.4.3(d) or indicates in such written notice that it does not wish to obtain a sublicense under the relevant Patent Rights, such Patent Rights are hereby deemed not to be Verve FTO Patent Rights or Patent Rights within the Verve Base Editing Technology, as the case may be, hereunder.

- 2.4.4 Verve shall be responsible for [**]. Any undisputed payment owed by Verve under this <u>Section 2.4.4</u> shall be made by Verve to Beam within [**] after receipt of invoice from Beam.
- 2.4.5 Beam shall be responsible for [**]. Any undisputed payment owed by Beam under this <u>Section 2.4.5</u> shall be made by Beam to Verve within [**] after receipt of invoice from Verve.

2.5 GalNAc License Option.

Verve hereby grants to Beam a non-exclusive right to obtain a license referred to in Section 2.1.4 (each, a 2.5.1 "GalNAc Opt-In Right"), which right Beam may exercise (in Beam's sole discretion) by providing Verve with written notice of such exercise (each, a "GalNAc Opt-In Exercise Notice") identifying one or more genes or biological targets other than Licensed Targets (each, a "GalNAc Target") for which it exercises its GalNAc Opt-In Right, provided that Beam may only exercise its GalNAc Opt-In Right with respect to a GalNAc Target that is Available (as determined in accordance with Section 2.5.2 or as otherwise agreed by the Parties in writing) and that is, as of delivery of the applicable Target Nomination Notice (as defined below), [**]. Upon and subject to Beam's exercise of a GalNAc Opt-In Right by Beam for an Available GalNAc Target (such GalNAc Target, a "Licensed GalNAc Target") including payment of the Target Nomination Fee, the license referred to in Section 2.1.4 shall automatically become effective, without the need of any amendment to this Agreement or further action by the Parties, and such Licensed GalNAc Target shall be added to Schedule 2.5.1, provided that the total number of Licensed GalNAc Targets may not exceed [**] at any given time; provided further that, on a Licensed GalNAc Target-by-Licensed GalNAc Target basis, [**], the applicable Licensed GalNAc Target shall no longer count towards the cap of [**] for the purpose of this sentence.

Within [**] of the Restatement Effective Date, Verve shall appoint an independent, nationally-recognized law 2.5.2 firm, reasonably acceptable to Beam, to act as a gatekeeper (the "Gatekeeper") solely for the purposes of verifying whether or not a proposed GalNAc Target is Available, as further described in this Section 2.5, and [**] shall bear all fees and costs the Gatekeeper incurred by the Parties in connection with the activities performed by the Gatekeeper in connection with this Agreement (within [**] following receipt of an invoice therefor). The Parties shall agree upon and enter into a customary three-way agreement with the Gatekeeper consistent with the terms of this Section 2.5. In accordance with such agreement, Verve will provide the Gatekeeper with an initial list of genes or biological targets that are not Available at the time of the entry into of such three-way agreement and will update the list of genes or biological targets that are not Available on a [**] basis or more frequently at its option. If Beam wants to exercise its GalNAc Opt-in Right for a given GalNAc Target, Beam shall notify the Gatekeeper in writing of the identity of such GalNAc Target at any time that is more than [**] after the Restatement Effective Date, or in relation to [**] only, at any time that is more than [**] after the Restatement Effective Date (a "Target Nomination Notice"). Following receipt of such notice, the Gatekeeper will request Verve to update the list most recently provided by Verve, determine whether the proposed GalNAc Target is Available using such updated list and inform Beam (and only Beam) of whether such GalNAc Target on the Target Nomination Notice is Available. If the Gatekeeper determines that a proposed GalNAc Target is not Available, at Beam's request, Verve shall provide the Gatekeeper with reasonable contemporaneous evidence that such proposed GalNAc Target is not Available, provided that Verve shall not be obligated to provide any confidential information of a Third Party. If the Gatekeeper determines that a proposed GalNAc Target is Available, the Gatekeeper shall notify Beam, and Beam may at its discretion (i) send a notice to Verve disclosing the identity of the Available GalNAc Target, in which case Verve shall not, for a period of [**] from the receipt of this notice, do anything or permit anything to be done that would render such GalNAc Target not Available and (ii) provide Verve with the GalNAc Opt-In Exercise Notice for such Available GalNAc Target pursuant to Section 2.5.1 and pay the Target Nomination Fee for such GalNAc Target concurrently with delivery of such GalNAc Opt-In Exercise Notice, provided that if Beam does not provide a GalNAc Opt-In Exercise Notice for an Available GalNAc Target within [**] after receipt of notice from the Gatekeeper of such GalNAc Target's Available status, then Beam must again comply with the procedures set forth in this Section 2.5.2 prior to exercising the GalNAc Opt-In Right with respect to such GalNAc Target. For clarity, each Target Nomination Notice shall be the Confidential Information of Beam, and the content of each list provided by Verve to the Gatekeeper pursuant to this Section 2.5.2 shall be the Confidential Information of Verve.

2.6 Exchange of Information; Technology Transfer.

2.6.1 Within [**] of the Restatement Effective Date (or such later date as set forth in <u>Schedule 2.6.1</u>), Verve shall complete the transfer to Beam of the Verve GalNAc

Know-How, Verve [**] Know-How, and Verve Lipid Know-How specifically used in the [**] Products Controlled by Verve prior to the Restatement Effective Date described in <u>Schedule 2.6.1</u> (the "Verve [**] Technology Transfer"). For a period no longer than [**] after the Restatement Effective Date, Verve shall make its personnel reasonably available to support such transfer. Verve shall answer questions (in a timely manner within such [**] period) from Beam relating to such transferred Know-How and provide Beam with reasonable support related to the Verve [**] Technology Transfer for up to [**] per week. Verve shall appoint a single individual as its technology transfer lead who shall act as Verve's lead for the timely and complete performance of all activities set forth in this <u>Section 2.6.1</u>.

- [**] within [**] of the Restatement Effective Date, and fails to cure such breach within [**] following written 2.6.2 notice of such breach provided by Beam within [**] of the Restatement Effective Date, Beam shall have the right, at its sole discretion, to terminate [**] as a Licensed Target, provided that such termination right shall expire if Beam does not provide Verve with written notice of such termination within [**] after expiration of such cure period. In addition, if Beam exercises such termination right, then: (a) Verve shall, within [**] following the date of such termination, assign, transfer, convey and deliver to Beam, all of Verve's right, title and interest in, to and under the [**] Patent Rights, and promptly execute an assignment of the [**] Patent Rights in forms registrable or recordable in the United States Patent and Trademark Office or applicable foreign offices to the extent necessary to assign the [**] Patent Rights, all in forms reasonably acceptable to Beam; (b) the license granted to Beam under Section 2.1.2 shall terminate effective as of the date of such termination; and (c) Beam shall, within [**] following the date of such termination, assign, transfer, convey and deliver to Verve, all of Beam's right, title and interest in, to and under the [**] Product-Specific Patent Rights, and promptly execute an assignment of the [**] Product-Specific Patent Rights in forms registrable or recordable in the United States Patent and Trademark Office or applicable foreign offices to the extent necessary to assign the [**] Product-Specific Patent Rights, all in forms reasonably acceptable to Verve. Upon such termination and until completion of the applicable assignment of Patent Rights referred to in this Section 2.6.2, the assigning Party hereby grants, and shall cause its Affiliates to grant, to the other Party a fully paid up, royalty free, irrevocable, perpetual exclusive (even as to such Party and its Affiliates) license under such Patent Rights, with a right to grant and authorize the further grant through multiple tiers of sublicenses for any and all purposes.
- 2.6.3 If, during the Term, (a) Verve desires that [**] Controlled by Beam or its Affiliates be added to the scope of the [**] or (b) Beam desires that [**] Controlled by Verve or its Affiliates be added to the scope of the [**], the Parties shall discuss such addition, provided that any such [**] shall only be added to the scope of the applicable definition upon the mutual written agreement of the Parties, in each case at each Party's sole discretion.

- 2.6.4 Notwithstanding anything to the contrary in this Agreement, neither Party has any obligation to disclose or transfer to the other Party any Know-How owned or otherwise Controlled by the Party except as expressly and specifically required by this Agreement or upon the mutual written agreement of the Parties, in each case at each Party's sole discretion.
- 2.6.5, Verve shall not disclose to Beam any Know-How owned or otherwise controlled by [**] or confidential information of [**]. In the event that this Agreement requires Verve to provide Beam with any Know-How owned or otherwise controlled by [**] or any confidential information of [**], prior to any disclosure thereof to Beam, Verve shall notify Beam and Beam shall decide, in its discretion, whether or not to accept the disclosure of such Know-How or confidential information. If Beam does not accept such disclosure, Verve and Beam shall cooperate in providing Beam with only a high-level nonconfidential summary of the applicable Know-How and the provision of such a summary shall constitute fulfilment by Verve of its obligation to provide Beam with the applicable Know-How.

2.7 Transfer of Materials.

- **Transfer**. A Party may agree under this Agreement (including the applicable Research Plan or Development Plan) to provide to the other Party, certain Know-How that are tangible compounds or biological materials (the "**Party Materials**"). Except as expressly set forth in this Agreement, the Party Materials are provided by the providing Party on an "as-is" basis without any representation or warranty of any type, express or implied, including any representation or warranty of merchantability, non-infringement, title or fitness for a particular purpose, each of which is hereby expressly disclaimed by the providing Party. A Party receiving Party Materials will not administer any such Party Materials to any human and will comply with all Applicable Laws applicable to the handling and use of such Party Materials.
- 2.7.2 Permitted Use of Party Materials. The Party receiving Party Materials from the other Party will use such Party Materials solely as contemplated in a Research Plan, Development Plan, or otherwise within the scope of the licenses granted to such receiving Party under this Agreement (including the rights to sublicense or transfer) (collectively, "Permitted Uses"). Without limiting the generality of the foregoing, except for Permitted Uses, the receiving Party of any Party Materials will not (a) make or attempt to make any analogues, progeny or derivatives of, or modifications to, such Party Materials or attempt to reverse engineer, or try to ascertain the identity, chemical structure, sequence, mechanism of action or composition of such Party Materials, or (b) use such Party Materials for such receiving Party's own benefit or for the benefit of any of its Affiliates or any Third Party. As to biological materials previously transferred to the other Party prior to the Restatement Effective Date, each receiving Party acknowledges that (a) the Party has not administered and will not administer any such Party

Materials to any human and has and will comply with all Applicable Laws applicable to the handling and use of such Party Materials, (b) the Party has not reversed engineered and will not reverse engineer any such Party Materials, (c) the Party has maintained any such materials as confidential, and (d) to the extent that the Party (or its Affiliates or persons acting on the Party's behalf) conceived, developed, generated or reduced to practice biological materials or compounds having similar or common structures or elements to the biological materials transferred to the Party, such activities were Permitted Activities and not precluded by the terms of the Original Agreement or any prior material transfer agreement. With respect to previously transferred biological materials, the transferring Party may at any time request the return of any remaining Party Materials.

- 2.7.3 <u>Unauthorized Use of Party Materials</u>. If any Party receives Party Material from the other Party after the Restatement Effective Date and uses such Party Material in any manner other than Permitted Uses, then any and all results of such unauthorized use, whether patentable or not, will belong solely and exclusively to the providing Party. Without limiting any other remedy that the providing Party of Party Materials may have under this Agreement or Applicable Law, the receiving Party of such Party Materials, on behalf of itself and its Affiliates, hereby assigns and agrees to assign to the providing Party all of the receiving Party's and its Affiliates' right, title and interest in and to all such discoveries and inventions arising from any such unauthorized uses of such Party Materials.
- 2.7.4 <u>Title to Party Materials; Return</u>. All right, title and interest in and to the Party Materials provided by a Party after the Restatement Effective Date under this Agreement will remain the sole and exclusive property of such providing Party notwithstanding the transfer to and use by the other Party of the same. At the end of the activities under this Agreement that relate to any Party Materials (including any termination of this Agreement in whole or in part), any Party who has received relevant Party Materials will either destroy or return to the providing Party, at such providing Party's sole discretion, all of such Party Materials that are unused.
- 2.7.5 <u>Material Transfer Agreement</u>. This Agreement supersedes and replaces that certain Material Transfer Agreement by and between the Parties dated as of [**], as amended (the "Material Transfer Agreement"). All Materials (as such term is defined in the Material Transfer Agreement) delivered to a Party by the other Party under the Material Transfer Agreement shall be deemed Party Materials of the respective providing Party hereunder and shall be so subject to the terms of this Agreement.

2.8 No Implied Licenses.

2.8.1 Except as expressly set forth in this Agreement, neither Party shall, by virtue of this Agreement, acquire any license or other intellectual property interest, by implication or otherwise, in (a) any information disclosed to it under this

Agreement, (b) any patents or patent applications Controlled or owned by the other Party or its Affiliates, (c) any trademarks (whether registered or protected by common law), trademark applications, or any goodwill associated with the foregoing Controlled or owned by the other Party or its Affiliates, or (d) any other intellectual property rights, however denominated, throughout the world, Controlled or owned by the other Party or its Affiliates.

2.9 Exclusivity.

- 2.9.1 During Term and for so long as [**] remains a Licensed Target, Verve and its Affiliates will not directly or indirectly (a) Develop, Manufacture, or Commercialize any gene editing product (other than an [**] Base Editor Product pursuant to this Agreement) that directly and selectively inhibits, activates or alters [**], or (b) license, authorize, appoint, or otherwise enable, whether directly or indirectly, any Third Party to conduct any of the foregoing activities, provided that Verve shall have the right to perform discovery and exploratory research (which for clarity excludes IND specific enabling toxicology activities) on therapeutic products that inhibit, activate or alter [**] that are not Base Editor Products.
- 2.9.2 Until the date that is [**] from the Restatement Effective Date, Verve and its Affiliates will not directly or indirectly (a) Develop or Commercialize any product (including any Base Editor Product or Nuclease Product) that directly and selectively inhibits, activates or alters [**], using any [**], or (b) license, authorize, appoint, or otherwise enable, whether directly or indirectly, any Third Party to conduct any of the foregoing activities.
- 2.9.3 Until the earlier of the expiration of the Term and termination of the licenses granted to Beam pursuant to Section 2.1.2 with respect to Verve [**] Technology, Verve and its Affiliates will not (except in the conduct of activities pursuant to this Agreement), directly or indirectly (a) Develop or Commercialize any product that directly and selectively inhibits, activates or alters [**], except that the foregoing restriction will terminate with respect to products that are not Base Editor Products [**] following the Restatement Effective Date or (b) license, authorize, appoint, or otherwise enable, whether directly or indirectly, any Third Party to conduct any of the foregoing activities.
- 2.9.4 On a product by product basis, if after the Restatement Effective Date and during the period of exclusivity set forth in Section 2.9.1, 2.9.2 and 2.9.3, Verve is acquired by a Third Party as a result of a Change of Control and such Future Acquirer is engaged in a Competitive Program or in the development or commercialization of a Competitive Product, immediately prior to or at any time after such Change of Control transaction, the Development or Commercialization of such Competitive Program or Competitive Product will not constitute a violation of Sections 2.9.1, 2.9.2, or 2.9.3 provided that during the period of exclusivity specified in Sections 2.9.1, 2.9.2, or 2.9.3: (i) [**]. For purposes of this Section 2.9.4, "Competitive Program" shall mean any research or

development program for which a budget has been established or to which research or development personnel have been assigned, with the goal of discovering or developing any product that directly and selectively alters (i) [**], (ii) [**] using any [**] or (iii) [**] (such product ((i), (ii) or (iii)), a "Competitive Product").

Article 3 MANAGEMENT; EXCHANGE OF INFORMATION

- **3.1** Collaboration Overview. The Parties desire and intend to collaborate with respect to the Development and Commercialization of Products in the Field in the Territory, as and to the extent set forth in this Agreement.
- **3.2 Limits on Committee Authority**. Each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in the JSC or any Subcommittee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. Notwithstanding anything to the contrary in this Agreement, in no circumstances shall the JSC or any Subcommittee have any power to amend, modify or waive compliance with this Agreement.
- **3.3 Joint Steering Committee**. As of the Restatement Effective Date, the Parties have established a joint steering committee (the "JSC") to facilitate communications between the Parties and oversee, review and manage the Development and Commercialization of Opt-In Products and Collaboration Products as set forth herein.
 - **Composition of the JSC**. The JSC shall be comprised of [**] of Verve and [**] of Beam. Each Party may change one or more of its representatives to the JSC from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with the Products and shall be duly authorized under their respective company's internal governance procedures to make the decisions or carry out the activities given to them under this Agreement.
 - **Specific Responsibilities**. In addition to its overall responsibility for monitoring and providing a forum to discuss and coordinate the Parties' activities under this Agreement, the JSC shall, subject to the terms of this Agreement, in particular:
 - (a) oversee the collaborative activities of the Parties under this Agreement;
 - (b) oversee the activities of Verve and Beam with respect to each Development Plan for Opt-In Products and Collaboration Products (including the Development Budget in any Development Plan for a Collaboration Product) and the Commercialization of Collaboration Product(s);
 - (c) review and decide whether to approve any proposed Development Plan for Opt-In Products and Collaboration Products (including the

- Development Budget in any Development Plan for a Collaboration Product) and any proposed amendments thereto:
- (d) oversee technology transfer activities to be carried out pursuant to <u>Section 2.6</u>;
- (e) oversee the activities of the Research Working Group;
- (f) review and decide whether to approve each proposed Commercialization Plan (including the Commercialization Budget in any Commercialization Plan) and any proposed amendments thereto;
- (g) with respect to Collaboration Products, approve pricing of such Products and supply thereof within the Collaboration Territory;
- (h) review CMC development and other Manufacturing activities for Opt-In Products (for which information shall be provided by Verve to the JSC in high-level, summary form only) and Collaboration Products for clinical and commercial use, subject to Section 2.6.5;
- (i) approve clinical supply plans for Opt-In Products and Collaboration Products and commercial supply plans for Collaboration Products;
- (j) review and decide whether to approve the designation of any costs or expenses as Post-Approval Shared Development Costs or Post-Approval Shared Regulatory Costs;
- (k) receive and discuss reports from Subcommittees and provide guidance thereto;
- (1) attempt to resolve issues presented to it by, and disputes within, any Subcommittee;
- (m) approve strategies for obtaining, maintaining, defending and enforcing trademark protection for Collaboration Products within the Collaboration Territory in accordance with the terms and conditions of Section 12.10.1(a);
- (n) approve all trademarks selected to be used to identify Collaboration Products and all trademarks, logos, taglines, trade dress, packaging configuration, domain names or indicia of origin for use in connection with the sale or marketing of Collaboration Products, in each case in the Collaboration Territory in accordance with the terms and conditions of Section 12.10.1(a);
- (o) review and decide whether to approve any other recommendations and submissions from the JDC and JCC;

- (p) establish such additional Subcommittees as it deems necessary to achieve the objectives and intent of this Agreement; and
- (q) have any other responsibility expressly designated for the JSC under this Agreement.
- 3.3.3 Decision-Making. Decisions of the JSC shall be made [**] by the representatives. In the event that the JSC cannot or does not, after good faith efforts, reach agreement on any issue, such issue shall be referred to the Alliance Managers. The Alliance Managers shall work with the JSC and use good faith commercially reasonable efforts to reach mutually acceptable resolutions on all such disputed matters. If the Alliance Managers are unable to assist the JSC in resolving such dispute within [**] after the dispute is first referred to the Alliance Managers, either Party may elect to submit such issue to the Parties' executive officers as follows: (i) for a Development-related issue, the issue shall be referred for resolution to the Development Senior Officers, or (ii) for a Commercialization-related issue, the issue shall be referred for resolution to the Commercialization Senior Officers. These executives are referred to collectively as the "Senior Officers". [**] and [**] have been designated by each Party by written notice to the other Party as of the Restatement Effective Date, and each Senior Officer of a Party may be changed by advance written notice by such Party to the other Party. In the event that the Senior Officers cannot resolve the issue, [**], with the following exceptions, all of which shall require agreement of the representatives of both Parties or the JSC or the agreement of both Senior Officers:
 - (a) For Opt-In Products:

[**].

(b) For Collaboration Products:

[**].

3.4 Research Working Group.

Composition of the Research Working Group. Within [**] after the Restatement Effective Date (or later if mutually agreed by the Parties), the Parties shall establish a research working group (the "**Research Working Group**"). Unless otherwise expressly agreed by the Parties in writing, the Research Working Group shall serve solely in an advisory capacity and have no independent decision-making authority. Each Party shall initially appoint [**] to the Research Working Group, with each representative having knowledge and expertise in the research of Base Editor products and being duly authorized under their respective company's internal governance procedures to carry out the activities given to them under this Agreement.

- **Specific Responsibilities of the Research Working Group**. The Research Working Group shall, subject to the terms of this Agreement, in particular:
 - (a) review and discuss each Research Plan, the progress of such Research Plan and any proposed amendments to such Research Plan;
 - (b) perform such other functions as may be appropriate to further the purposes of this Agreement, as directed by the JSC or as set forth under this Agreement.

3.5 Joint Development Committee.

- 3.5.1 Composition of the Joint Development Committee. Prior to the earlier of [**] following a decision by the JSC that a joint development committee would be appropriate given the stage of Development of one or more Licensed Products and (b) [**] after Verve submits an initial development plan in accordance with Section 4.3.1 for the first Licensed Product, the Parties shall establish a committee to oversee Development of Products and to coordinate the Development and regulatory activities of the Parties with respect to such Products (the "JDC"). Unless otherwise expressly provided in this Agreement or agreed by the Parties in writing, the JDC shall serve solely in an advisory capacity and have no independent decision-making authority. Each Party shall initially appoint [**] to the JDC, with each representative having knowledge and expertise in the development of products or in obtaining and maintaining Marketing Authorizations of products, having sufficient seniority within the applicable Party to make decisions arising within the scope of the JDC's responsibilities and being duly authorized under their respective company's internal governance procedures to make the decisions or carry out the activities given to them under this Agreement. The Parties may agree to increase the number of representatives from each Party on the JDC; provided, however, that the JDC shall at all times be comprised of an equal number of representatives from each Party.
- **3.5.2** Specific Responsibilities of the JDC. In addition to its general responsibilities, the JDC shall, subject to the terms of this Agreement, in particular:
 - (a) discuss, prepare and approve for submission to the JSC any Development Plan, and any amendments to a Development Plan (including, for Collaboration Products, the Development Budget under a Subsequent Development Plan);
 - (b) with respect to Collaboration Products, if any, review and update [**] financial forecasts for Development, including regulatory activities, to ensure actual and anticipated expenditure is within the approved Development Budget for the relevant Calendar Year, and make recommendations to the JSC for approval regarding any variances before such additional expenditure is incurred;

- (c) create, approve for submission to the JSC, and implement the overall strategy for Development and the design and objectives of all Clinical Trials and non-clinical studies conducted under each Development Plan;
- (d) advise the JSC on whether and when to Initiate or discontinue, and the conduct of, any Clinical Trial and any non-clinical study under each Development Plan;
- (e) facilitate the flow of information between the Parties with respect to Development and Marketing Authorizations of the Collaboration Products in the Territory;
- (f) discuss and approve for submission to the JSC the overall regulatory and filing strategy for obtaining Marketing Authorization for Collaboration Products in the Territory and for maintaining such Marketing Authorization including post-approval commitments and life cycle management;
- (g) advise the JSC on the submission of the NDAs for the Collaboration Products;
- (h) review, coordinate and approve for submission to the JSC the scientific presentation and publication strategy relating to the Collaboration Products in the Territory; and
- (i) perform such other functions as may be appropriate to further the purposes of this Agreement, as directed by the JSC or as specified in this Agreement.
- **Decision-Making**. The JDC shall act by [**] consent. The representatives from each Party will have, collectively, [**] on behalf of that Party. If the JDC cannot reach [**] consent on an issue that comes before the JDC and over which the JDC has oversight, then such matter shall be raised to the JSC for resolution in accordance with Section 3.3.3.

3.6 Joint Commercialization Committee.

2.6.1 Composition. The Parties shall establish a committee to oversee Commercialization of Collaboration Products (other than commercial manufacture and Product distribution) in the Collaboration Territory (the "JCC") at such time as may be determined by the JSC, but in no event later than [**] after the Initiation of the first Phase III Clinical Trial of a Collaboration Product. Unless otherwise expressly provided in this Agreement or agreed by the Parties in writing, the JCC shall serve solely in an advisory capacity and have no independent decision-making authority. Each Party shall initially appoint [**] to the JCC, with each representative having knowledge and expertise in the commercialization of products similar to the Collaboration Products, having sufficient seniority within the applicable Party to make decisions arising within

the scope of the JCC's responsibilities and being duly authorized under their respective company's internal governance procedures to make the decisions or carry out the activities given to them under this Agreement. The Parties may agree to change the number of representatives from each Party on the JCC; <u>provided</u>, <u>however</u>, that the JCC shall at all times be comprised of an equal number of representatives from each Party.

- **Specific Responsibilities of the JCC**. In addition to its general responsibilities, the JCC shall in particular:
 - (a) discuss, prepare and approve for submission to the JSC all Commercialization Plans (including the Commercialization Budget), including any amendments thereto;
 - (b) review and update revenue forecasts and review the Commercialization Budget for Collaboration Products in the Collaboration Territory at least on a [**] basis (or as otherwise agreed by the JCC) to ensure actual and anticipated expenditure is within the approved Commercialization Budget for the relevant Calendar Year, and make recommendations to the JCC for approval regarding any variances before such additional expenditure is incurred;
 - (c) review and discuss the Commercialization activities (including Co-Promotion) of Beam and Verve with respect to Collaboration Products in the Collaboration Territory;
 - (d) prepare forecasts of relevant Collaboration Products to be shared with the JMC for planning of inventory levels of such Products;
 - (e) subject to the terms and conditions of Section 12.10.1, discuss and approve for submission to the JSC the appropriate timing for selection of trademarks, and discuss, review and approve for submission to the JSC all proposed trademarks cleared by the Parties selected to be used to identify Collaboration Products in the Collaboration Territory and all proposed trademarks, logos, taglines, trade dress, packaging configuration, domain names or indicia of origin, in each case, cleared by the Parties for use in connection with the sale or marketing of Collaboration Products in the Collaboration Territory;
 - (f) review, discuss, coordinate and approve for submission to the JSC, in the Collaboration Territory, the Parties' medical affairs activities with respect to the Collaboration Products; and
 - (g) perform such other functions as appropriate to further the purposes of this Agreement, as directed by the JSC or as specified in this Agreement.
- **Decision-Making**. The JCC shall act by [**] consent. The representatives from each Party will have, collectively, [**] on behalf of that Party. If the JCC cannot

reach [**] consent on an issue that comes before the JCC and over which the JCC has oversight, then such matter shall be raised to the JSC for resolution in accordance with <u>Section 3.3.3</u>.

3.7 Alliance Managers.

- Appointment. Each Party shall have the right to appoint an employee who shall oversee interactions between the Parties for all matters related to this Agreement and any related agreements between the Parties or their Affiliates (each an "Alliance Manager"). Such persons shall endeavor to assure clear and responsive communication between the Parties and the effective exchange of information, and may serve as a single point of contact for any matters arising under this Agreement. The Alliance Managers shall have the right to attend all JSC and Subcommittee meetings as non-voting participants and may bring to the attention to the JSC or any Subcommittee any matters or issues either of them reasonably believes should be discussed, and shall have such other responsibilities as the Parties may mutually agree in writing. Each Party may designate different Alliance Managers by notice in writing to the other Party.
- **Responsibilities of the Alliance Managers**. Without limiting the generality of the foregoing, each Alliance Manager shall:
 - (a) identify and bring disputes and issues that may result in disputes (including without limitation any asserted occurrence of a material breach by a Party) to the attention of the JSC in a timely manner, and function as the point of first referral in all matters of conflict resolution;
 - (b) provide a single point of communication for seeking consensus both internally within the Parties' respective organizations and between the Parties;
 - (c) plan and coordinate cooperative efforts, internal communications and external communications between the Parties with respect to this Agreement; and
 - (d) take responsibility for ensuring that meetings and the production of meeting agendas and minutes occur as set forth in this Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.
- 3.7.3 The Parties shall meet within [**] of the Restatement Effective Date and discuss in good faith any additional modifications to the information sharing and governance provisions of this Agreement including those in this Article 3, with the objective of streamlining governance to ensure appropriate information sharing between the Parties. In addition, the Parties agree to use good faith reasonable efforts to complete a relaunch of the alliance management function within [**] of the Restatement Effective Date with the objective to ensure an

- 3.8 Committee Size and Composition; Observers. The JSC and any Subcommittee may change its size from time to time by mutual, [**] consent of its members, <u>provided</u> that the JSC and each Subcommittee shall consist at all times of an equal number of representatives of each of Verve and Beam. Each Party may replace one or more of its JSC or Subcommittee representatives at any time upon written notice to the other Party. The JSC or any Subcommittee may invite non-members (including consultants and advisors of a Party who are under an obligation of confidentiality consistent with this Agreement) to participate in the discussions and meetings of such Committee, <u>provided</u> that such participants are involved in activities related to the business of such Committee and shall have no voting authority at such Committee.
- **3.9 Chairpersons**. Each Committee shall be chaired by a representative of [**]. The role of the chairperson shall be to convene and preside at meetings of the Committee, as applicable, to prepare and circulate agendas and to ensure the preparation of minutes, but the chairperson shall have no additional powers or rights beyond those held by the other representatives of the Committee, as applicable.
- **3.10 Committee Meetings**. Each Committee shall meet at least [**] at a time mutually agreed by the Parties, spaced at regular intervals unless the Parties mutually agree to a different frequency. Each Committee may meet in person, or at the request of either Party, by videoconference, teleconference or other similar communications equipment. In-person Committee meetings will be held at locations alternately selected (as within a Committee) by Verve and by Beam. Either Party may also call a special meeting of a Committee (by videoconference or teleconference) by at least [**] prior written notice to the other Party in the event such requesting Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, and such requesting Party shall provide such Committee no later than [**] prior to the special meeting with materials reasonably adequate to enable an informed decision on the relevant matter: provided that for time sensitive matters, a Party may call a special meeting of such Committee and provide relevant materials with less than [**] notice if the Parties agree that an issue warrants an expedited meeting. No later than [**] prior to any meeting of a Committee (other than a special meeting as described above), the Alliance Managers shall prepare and circulate an agenda for such meeting to all members of such Committee; provided, however, that either Party shall be free to propose additional topics to be included on such agenda, either prior to or, if representatives of each Party are present at a meeting, during the course of such meeting. Each Party will bear the expense of its respective Committee members' participation in Committee meetings. The Alliance Managers shall be responsible for keeping reasonably detailed written minutes of such Committee's meetings that reflect all decisions made at such meetings. The Alliance Managers shall send meeting minutes to each member of such Committee for review and approval within [**] after each meeting of such Committee. Minutes will be deemed approved unless [**] members of the relevant Committee objects to the accuracy of such minutes within [**] of receipt.

3.11 Safety Reporting.

- 3.11.1 The Parties shall agree upon a pharmacovigilance agreement (the "Pharmacovigilance Agreement") for exchanging adverse event and other safety information relating to a Licensed Product prior to either Party's initiation of any clinical activities implicating pharmacovigilance obligations for such Licensed Product in the Territory. The Pharmacovigilance Agreement shall ensure that adverse event and other safety information is exchanged according to a schedule that will permit each Party to comply with Applicable Laws, including any local regulatory requirements and all applicable privacy laws.
- 3.11.2 Each Party shall use and disclose any information relating to an individual person, including but not limited to Clinical Trial Data or adverse event or other safety information, in compliance with Applicable Law, including the European General Data Protection Regulations. If required by Applicable Law, the Parties shall negotiate and execute a data protection agreement reasonably acceptable to both Parties, prior to using or disclosing any such information.

3.12 Records and Reports.

- **Records**. Each Party shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes under Applicable Law, which shall fully and properly reflect all work done and results achieved by such Party under this Agreement.
- **Copies and Inspection of Records**. Each Party shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all records of the other Party referred to in Section 3.12.1. The reviewing Party shall maintain such records and the information disclosed therein in confidence in accordance with Section 10.1. Upon request, the non-reviewing Party shall provide copies of the records described in this Section 3.12.2.

3.13 Compliance with Law and Ethical Business Practices.

- 3.13.1 In conducting its activities under this Agreement, each Party shall comply in all material respects with Applicable Law and accepted pharmaceutical industry business practices, including, without limitation, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, et seq.), the Anti-Kickback Statute (42 U.S.C. § 1320a-7b), Civil Monetary Penalty Statute (42 U.S.C. § 1320a-7a), the False Claims Act (31 U.S.C. § 3729 et seq.), comparable state statutes, the regulations promulgated under all such statutes, the regulations issued by the FDA, and all applicable privacy laws and regulations. Each Party shall promptly notify the other Party in writing of any material deviations from Applicable Law with respect to activities under this Agreement of which it becomes aware.
- 3.13.2 Each Party hereby certifies that it has not and will not employ or otherwise use in any capacity the services of any person or entity debarred under Section 21 U.S.C. § 335a in performing any activities under this Agreement. Each Party shall notify the other Party, in writing, immediately if any such debarment occurs or comes

to its attention, and shall, with respect to any person or entity so debarred, promptly remove such person or entity from performing any further activities under this Agreement.

3.13.3 No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates any Applicable Law.

Article 4 RESEARCH AND DEVELOPMENT

4.1 General Obligations.

- 4.1.1 Each Party shall use Commercially Reasonable Efforts to conduct the activities for which it is responsible under any Research Plan and Development Plan. All Development activities of the Parties relating to the Development of Licensed Product(s) in the Territory will be performed in accordance with this Agreement. In addition, following initiation of activity under a Research Plan, Verve shall use Commercially Reasonable Efforts to Develop and seek Marketing Authorization for [**].
- 4.1.2 Verve shall initiate discovery efforts for a Base Editor Product directed towards [**] within [**] of the Restatement Effective Date pursuant to the Research Plan for [**]. Verve shall use Commercially Reasonable Efforts to Develop and seek Marketing Authorization for [**].
- **4.1.3** With respect to any Licensed Product for which Beam has an Opt-In Option, but does not, and can no longer under the terms of this Agreement, exercise the Beam Opt-In Option, Section 4.1.1 shall not apply, except that Verve shall still be subject to the last sentence of Section 4.1.1 which sets forth certain diligence obligations and shall perform, and cause to be performed, all Development activities related to such Licensed Product in the Territory in accordance with this Agreement.
- 4.1.4 Without limiting any other provision of this Agreement, Verve agrees that, to the extent applicable to its contemplated activities under this Agreement, it shall satisfy the diligence obligations set forth in Schedule 4.1.4 related to Development applicable to sublicensees of Beam Base Editor Technology under Third Party Agreements to which Beam or its Affiliate is a party. Schedule 4.1.4 may be amended from time to time by Beam upon written notice to Verve in the event Beam reasonably determines that additional diligence obligations under Third Party Agreements to which Beam or its Affiliate is a party relate to the Development activities of Verve hereunder as a sublicensee of Beam Base Editor Technology, subject to compliance with Sections 2.4.3 with respect to any such Third Party Agreements entered into after the Restatement Effective Date and provided that any such additional diligence obligations shall only apply following the date of such amendment. Either Party may perform its obligations under this Agreement through Third Party subcontractors; provided that [**]. Any efforts

of Verve or its Affiliates and sublicensees shall be deemed to be the efforts of Verve for purposes of satisfying the diligence requirements of this Agreement.

4.2 Research Plan. Within [**] following the Restatement Effective Date, Verve shall provide to Beam an initial research plan for Licensed Products [**] (which shall include at least the activities and objectives set forth in this Section 4.2) and research activities for PCSK9 or ANGPTL3, as applicable (each such research plan, as amended from time to time under this Agreement, a "**Research Plan**"). Each Research Plan shall consist of [**]. Verve shall present each Research Plan and amendment or updates thereof, and on a [**] basis, the progress under each Research Plan, to Beam, through the Research Working Group, and shall consider Beam's comments thereon in good faith.

4.3 Development Plans.

4.3.1 <u>Initial Development Plan</u>. Within the later of (a) [**] prior to the anticipated IND submission for a Licensed Product or (b) as to a Licensed Product directed to PCSK9, [**] after the Restatement Effective Date, Verve shall, to the extent applicable, submit to the JDC and/or JSC an initial development plan for [**] (such development plan once recommended for approval by the JDC and approved by the JSC, the "Initial Development Plan"). An Initial Development Plan may only be amended with the approval of the JSC in accordance with this Agreement, and each such amendment shall [**]. An Initial Development Plan shall be effective from the date on which it is approved by the JSC and shall terminate when all activities under such Initial Development Plan have been completed or, if earlier, as of the date upon which Beam exercises the Beam Opt-In Option with respect to the applicable Opt-In Product pursuant to Section 5.1. For the avoidance of doubt, subject to the exceptions set forth in clauses (a) and (b) of Section 3.3.3, [**].

4.3.2 <u>Subsequent Development Plan; Subsequent Development Updates.</u>

- (a) Subject to Section 4.3.2(b), with respect to any Collaboration Product, there shall be a "Subsequent Development Plan" for such Collaboration Product that includes [**]. Notwithstanding any provision in this Agreement to the contrary, in the event Beam exercises a Beam Opt-In Option upon receipt of an [**] for a Collaboration Product, the Subsequent Development Plan for such Collaboration Product will additionally include [**], such additional activities to be conducted at Verve's sole cost and expense, in accordance with Section 5.1.
- (b) For any Opt-In Product for which Beam does not exercise the Beam Opt-In Option, or commencing as of the applicable Opt-Out Date for any Collaboration Product, there shall be no Subsequent Development Plan but Verve shall update Beam every [**] (beginning [**] after Beam's failure to exercise the Beam Opt-In Option for any such Opt-In Product that is a Licensed Product or, with respect to any Collaboration Product for which Beam exercises the Beam Opt-Out Option, [**] after the

applicable Beam Opt-Out Date, as the case may be) on the Development of such Licensed Product until the First Commercial Sale of such Licensed Product or until Development activities for such Licensed Product have ended, whichever occurs earlier. Such update shall consist of [**]. Upon request by Beam, the Parties shall meet, either in-person or via videoconference or teleconference, to discuss such status update and Verve shall consider in good faith the implementation of any reasonable comment by Beam with respect to the Development of such Licensed Product.

- (c) Notwithstanding anything to the contrary in this Agreement, Verve may not conduct any Development activity with respect to a Licensed Product that is not a Collaboration Product that, [**].
- 4.3.3 Amendments to the Development Plan. On [**] basis, the JDC shall evaluate whether any amendment to the then-current Development Plans, and, subject to this Agreement, the corresponding Development Budget if applicable, are appropriate to reflect [**]. In the event that such amendment is deemed necessary, the JDC shall submit such amendment for approval of the JSC no later than [**] of the preceding Calendar Year. Each such amended Development Plan shall contain [**]. In addition, the JDC may prepare amendments to the Development Plan and any Development Budget (if applicable) for the JSC's approval from time to time during a Calendar Year in order to reflect changes in such plan and budget allocations for such Calendar Year, in each case, in accordance with the foregoing. Once approved by the JSC, the amended [**] Development Plan (including the Development Budget, if any) shall become effective for the applicable period on the date approved by the JSC (or such other date as the JSC shall specify). Any JSC-approved amended Development Plan (including, as applicable, any amended Development Budget) for a Product shall supersede the previous Development Plan and Development Budget for such Product.
- **4.3.4 Discontinued Development; Inconsistency**. If the JSC determines to discontinue Developing a Licensed Product or Collaboration Product upon recommendation by the JDC or otherwise in accordance with this Agreement, then any Development Plan (and the associated Development Budget, if applicable) solely related to such Licensed Product or Collaboration Product, as the case may be, shall terminate upon such decision. In the event of any inconsistency between the applicable Development Plan and this Agreement, the terms of this Agreement shall prevail.
- **4.4 Development Costs**. Except with respect to Shared Costs for Collaboration Products as described in <u>Section 9.5.1</u>, as between the Parties, [**].

Article 5 BEAM OPT-IN OPTION

5.1 Opportunity to Opt In. For any Opt-In Product, Beam will have the option with respect to such Opt-In Product to opt-in to share expenses of the Development of such Opt-In Product in the Territory, jointly Commercialize such Opt-In Product in the Collaboration Territory and share the profits and expenses of Commercializing the Opt-In Product in the Collaboration Territory, in each case on the terms set forth in this Agreement (such option with respect to an Opt-In Product, the "Beam Opt-In Option" for such Opt-In Product). On an Opt-In Product-by-Opt-In Product basis, within [**] of the final dosing of the final patient in a Phase I Clinical Trial of such Opt-In Product, Verve will deliver to Beam an information package for such Opt-In Product, such information package to include the following information (the "Opt-In Information Package"):

[**].

To the extent that any additional information or data is necessary for Beam, acting in good faith, to make an informed decision regarding whether to exercise the Beam Opt-In Option for such Opt-In Product, the Opt-In Information Package shall also include other information, data, or materials (i) directly related to such Opt-In Product, (ii) possessed and Controlled by Verve or its Affiliates, and (iii) requested by Beam within [**] of the receipt of the information described in clauses 5.1.1 through 5.1.5 above; provided that Verve shall not have any obligation to perform any additional studies or experiments to respond to any request made pursuant to this paragraph. [**]. During the [**] period following delivery of an Opt-In Information Package for an Opt-In Product, at Beam's request, the Parties will work together in good faith in an effort to reach written agreement on a Subsequent Development Plan for such Opt-In Product, including the related Development Budget. Beam will have [**] from receipt of the complete Opt-In Information Package to determine whether it is interested in participating in future Development and Commercialization of such Opt-In Product on the terms and conditions set forth in this Agreement for Collaboration Products. Beam may exercise the Beam Opt-In Option with respect to an Opt-In Product at any time during such [**] period by written notice to Verve. [**].

5.2 Subsequent Development Plan; Election Not to Opt-In.

- 5.2.1 With respect to any Opt-In Product, in the event that Beam exercises the Beam Opt-In Option for such Opt-In Product pursuant to Section 5.1, (a) the agreed-upon Subsequent Development Plan shall become the Subsequent Development Plan for such Opt-In Product and (b) such Opt-In Product shall become a Collaboration Product under this Agreement.
- 5.2.2 With respect to any Opt-In Product, in the event that Beam does not exercise the Beam Opt-In Option for such Opt-In Product in the applicable [**] window pursuant to Section 5.1, such Opt-In Product shall not become a Collaboration Product under this Agreement and the Beam Opt-In Option for such Opt-In Product shall thereupon terminate, [**].

- 5.3 Beam Opt-Out Option. With respect to each Collaboration Product, Beam may opt out of payment of Shared Development Costs, Shared Commercialization Costs, sharing of Collaboration Territory Revenue and participation in Commercialization of such Collaboration Product under this Agreement ("Beam Opt-Out Option"), upon written notice to Verve. In the event Beam elects the Beam Opt-Out Option for a Collaboration Product, effective as of [**] following the delivery of such written election to Verve (the "Beam Opt-Out Date"), (a) such Collaboration Product will no longer be a Collaboration Product under this Agreement, (b) royalties and milestones for such former Collaboration Product under this Agreement, if applicable, including under Sections 9.2.1, 9.3 and 9.4.1, shall become effective and payable by Verve going forward as if Beam had never exercised the Beam Opt-In Option for such Product, (c) Verve shall pay Beam a milestone payment equal to [**] the Shared Costs for such former Collaboration Product that Beam has paid under this Agreement, such milestone payment to be made within [**] after aggregate Net Sales of such former Collaboration Product in a Calendar Year in the Territory first reach [**] Dollars (\$[**]), (d) subject to this Section 5.3. Beam shall no longer have any obligation to pay any portion of Shared Costs incurred following the Beam Opt-Out Date for such former Collaboration Product and (e) Beam shall no longer have the right to Commercialize. including Co-Promote, such former Collaboration Product. Notwithstanding anything to the contrary in this Section 5.3, if Beam elects the Beam Opt-Out Option for a Collaboration Product during the conduct of a Clinical Trial for such Collaboration Product, it shall remain responsible for the Shared Costs reasonably incurred in the conduct of such Clinical Trial under this Agreement as if such Collaboration Product remained a Collaboration Product for the duration of such Clinical Trial.
- Verve Opt-Out Option. With respect to each Collaboration Product, Verve may opt out of payment of Shared Development Costs, Shared Commercialization Costs, sharing of Collaboration Territory Revenue and participation in Commercialization of such Collaboration Product under this Agreement ("Verve Opt-Out Option"), upon written notice to Beam. In the event Verve elects the Verve Opt-Out Option for a Collaboration Product, effective as of [**] following the delivery of such written election to Verve (the "Verve Opt-Out Date"), (a) such Collaboration Product will no longer be a Collaboration Product under this Agreement, (b) such former Collaboration Product shall be deemed to be a Terminated Reversion Product (including, for clarity, any such former Collaboration Product that is not a Licensed Product) for purposes of Section 14.6 as if Verve had terminated such Product under clause (b) of Section 14.2; provided, however, that any license granted by Verve pursuant to Section 14.6.2(b) with respect to such Product shall be royalty-free and fully paid up, except with respect to payment of any amounts owed to a Third Party pursuant to an applicable license or other agreement as set forth in Section 14.6.2(b), (c) Beam shall pay Verve a milestone payment equal to the sum of (i) the FTE Costs and out-of-pocket costs (including Third Party Payments) incurred by Verve for the conduct of the Phase I Clinical Trial in accordance with the Initial Development Plan for such Collaboration Product and (ii) [**] times the Shared Costs for such former Collaboration Product that Verve has paid under this Agreement, such milestone payment to be made within [**] after aggregate Net Sales of such former Collaboration Product in a Calendar Year in the Territory first reach [**] Dollars (\$[**]), (d) subject to this Section 5.4, Verve shall no longer have any obligation to pay any portion of Shared Costs incurred following the Verve Opt-Out Date for such former Collaboration Product and (e) Verve

shall no longer have the right to Commercialize, including Co-Promote, such former Collaboration Product. Notwithstanding anything to the contrary in this <u>Section 5.4</u>, if Verve elects the Verve Opt-Out Option for a Collaboration Product during the conduct of a Clinical Trial for such Collaboration Product, it shall remain responsible for the Shared Costs reasonably incurred in the conduct of such Clinical Trial under this Agreement as if such Collaboration Product remained a Collaboration Product for the duration of such Clinical Trial.

5.5 Discussion of Proposal. [**].

Article 6 REGULATORY RESPONSIBILITY

- 6.1 General. Verve or its designee shall have sole responsibility and discretion in formulating the regulatory strategy for any Nuclease Product or Base Editor Product that, in each case, is not either a Collaboration Product or Opt-In Product. Verve shall keep Beam informed as to material developments related to interactions by it, its Affiliates or sublicensees with Regulatory Authorities with respect to Collaboration Products and Opt-In Products under this Agreement. Verve shall promptly notify (but in any event within [**]) Beam upon becoming aware of any actual or potential Safety Issue or serious adverse event with respect to one or more Collaboration Products.
- **6.2 Opt-In Products and Collaboration Products**. The regulatory strategy for each Collaboration Product and Opt-In Product shall be formulated by Verve, subject to oversight by the JSC in accordance with Section 3.3. In reviewing the regulatory strategy for each Collaboration Product and Opt-In Product, Verve shall consider and determine whether to incorporate in good faith Beam's reasonable comments with respect to same. Verve shall be responsible for taking the lead with the request and conduct of all interactions with Regulatory Authorities (meetings, telephone calls, etc.) in the Territory. Beam shall be entitled to have a non-participating representative present at such scheduled interactions, with respect to Opt-In Products and Collaboration Products, with Regulatory Authorities in the Territory, provided that at Verve's request, the Beam representative shall step out of any portions of such interactions that do not relate to the Opt-In Products or Collaboration Products. As between the Parties, Verve shall be responsible for preparing all submissions, documents or other correspondence submitted to applicable Regulatory Authorities for such Products in the Territory (collectively, the "Regulatory Documentation"), and Verve or its designee(s) shall own all Regulatory Documentation, INDs, NDAs and Marketing Authorizations with respect to Products. Beam shall have the right to review and comment on all Regulatory Documentation for Collaboration Products, and Verve shall reasonably consider and[**] implement any comments provided by Beam with respect to such Regulatory Documentation. Verve or its designee(s) shall also be responsible for all maintenance of all INDs and all NDAs related to Products, provided that, with respect to Collaboration Products, the FTE Costs and out-of-pocket costs that are incurred by Verve or its Affiliates in connection with such maintenance in the Major Markets shall be Shared Development Costs. Beam shall maintain all Confidential Information of Verve gained in connection with its rights under this Section 6.2 in strict confidence and shall not use for any other purpose other than in connection with the

Development and Commercialization of the Licensed Product that is the subject of these activities and no other program, in each case in accordance with <u>Article 10</u>.

Article 7 COMMERCIALIZATION

- **7.1 Commercialization Efforts**. Each Party shall conduct the activities for which it is responsible under the applicable Commercialization Plan. Verve shall use Commercially Reasonable Efforts to Commercialize Licensed Products, and Verve and Beam shall use Commercially Reasonable Efforts to Commercialize Collaboration Products, in each case in the Field in the Major Markets in which Marketing Authorization has been obtained, as further described in this <u>Article 7</u>.
- 7.2 Commercialization of Product(s). All Commercialization activities of the Parties with respect to Collaboration Products in the Collaboration Territory will be performed under the direction of the JCC and the JSC in accordance with the then-current applicable Commercialization Plan. In the event of any inconsistency between a Commercialization Plan or a Commercialization Budget and this Agreement, the terms of this Agreement shall prevail unless otherwise expressly set forth in the relevant Commercialization Plan or Commercialization Budget. Verve will keep the JCC informed of Commercialization activities of Verve with respect to Licensed Products and Collaboration Products outside the Collaboration Territory, and Verve will deliver to Beam on a [**] basis a written report summarizing its material Commercialization activities with respect to Licensed Products that are not Collaboration Products and with respect to Collaboration Products outside the Collaboration Territory, such reports to be sufficient in content to allow Beam to evaluate whether Verve has satisfied its diligence obligations with respect to such Collaboration Products in accordance with Section 7.1. Verve shall ensure that any Third Party, including a sublicensee, that undertakes Commercialization activities with respect to a Licensed Product or Collaboration Product permits disclosure of all relevant information to Beam in the reports described in this Section 7.2.

7.3 Commercialization Plan.

- 7.3.1 Within [**] after the Initiation of a Phase III Clinical Trial of a Collaboration Product in the Field in the Territory, the JCC shall develop an initial high-level Commercialization plan for the Collaboration Products in the Field in the Collaboration Territory (such plan, if and when approved by the JSC and as may be amended from time to time in accordance with this Agreement, the "Commercialization Plan").
- **7.3.2** Each Commercialization Plan shall contain, as applicable: [**].
- **7.4** Commercialization Reports. Each Party shall keep the JCC fully informed regarding the progress and results of Commercialization activities for Collaboration Products in the Collaboration Territory conducted by such Party, including a [**] review of activities undertaken versus the Commercialization Plan for such Collaboration Products.
- **7.5** Commercialization Costs. Subject to Section 9.5.1(b), as between the Parties, Verve shall be solely responsible for all costs and expenses incurred (including both internal

FTE-based costs and payments owed to Third Parties) in the conduct of activities under any Commercialization Plan.

7.6 Co-Promotion. With respect to each Collaboration Product, the Parties shall enter into an agreement that sets forth the terms of the Parties' Co-Promotion of such Collaboration Products in the Collaboration Territory no later than [**] prior to the anticipated First Commercial Sale of such Collaboration Product in the Collaboration Territory, such terms to be consistent with the high-level terms and principles set forth in this Section 7.6 (each such agreement, a "Co-Promotion Agreement"). The Parties shall Co-Promote the Collaboration Products in the Collaboration Territory pursuant to the terms and conditions of this Agreement and the applicable Co-Promotion Agreement, provided that Verve shall book all sales of Collaboration Products in the Collaboration Territory. Any Co-Promotion Agreement entered into by the Parties pursuant to this Section 7.6 will set forth the terms under which Beam will engage in the Co-Promotion of such Collaboration Product with Verve to primary care physicians, specialists, and other agreed target customers or stakeholders in the Collaboration Territory. Each Party will provide fifty percent (50%) of the promotional effort required to promote the Collaboration Product in the Collaboration Territory at launch and throughout Commercialization in this Agreement and the allocation of the promotional effort between the Parties will be made on an equitable basis as to both the quality and quantity of the activities to be undertaken, including the identity of target prescribers and the nature of the Details. Costs incurred by the Parties for Co-Promotion activities under the Co-Promotion Agreement shall be Shared Commercialization Costs unless otherwise mutually agreed by the Parties and expressly set forth in the Co-Promotion Agreement. For clarity, the applicable Co-Promotion Agreement shall automatically be terminated on the applicable Opt-Out Date in the event Beam exercises a Beam Opt-Out Option or Verve exercises a Verve Opt-Out Option with respect to a particular Collaboration Product.

Article 8 MANUFACTURING

8.1 General. Except as otherwise expressly agreed by the Parties in writing with respect to Collaboration Products, Verve shall have sole authority over and control of the Manufacture of Products, itself or through one or more Affiliates or Third Parties selected by Verve, in accordance with any applicable Subsequent Development Plan or Commercialization Plan, as the case may be.

Article 9 PAYMENTS AND CONSIDERATION; EQUITY PURCHASE

9.1 Initial Issuance. In accordance with the terms of the Subscription Agreement entered into by the Parties on the Original Agreement Effective Date and concurrently with the execution of the Original Agreement, as partial consideration for the licenses granted hereunder, issued to Beam an aggregate of 2,556,322 shares of Verve's common stock.

9.2 Development Milestone Payments.

9.2.1 In further consideration for the licenses granted herein by Beam to Verve, upon the terms and conditions contained herein, Verve shall pay to Beam the milestone payment set forth in the table below for each Licensed Product that achieves the corresponding milestone event:

Milestone Event	For any Licensed Product that is not a Collaboration Product, in the Territory	For any Licensed Product that is a Collaboration Product, outside the Collaboration Territory
[**]	[**] U.S. Dollars (\$[**])	[**] U.S. Dollars (\$[**])
[**]	[**] U.S. Dollars (\$[**])	[**] Dollars (\$[**])
[**]	[**] U.S. Dollars (\$[**])	[**] U.S. Dollars (\$[**])

Verve shall notify Beam in writing within [**] following the achievement of each milestone, and shall make the appropriate milestone payment within [**] after the achievement of such milestone. All milestone payments are payable only once under this Agreement for each Licensed Product to achieve such milestone. If a milestone set forth in the table in this Section 9.2.1 is skipped (e.g. [**]), the payment associated with such skipped milestone shall be paid when the subsequent milestone is achieved in addition to the payment that would otherwise be due upon achievement of such subsequent milestone.

9.2.2 In further consideration for the licenses granted by Verve to Beam under Section 2.1.4, respectively, upon the terms and conditions contained herein, Beam shall pay Verve the milestone payment once for each Licensed GalNAc Target (other than [**]) upon the first achievement of the corresponding milestone event as set forth in the table below:

Milestone Event	Milestone Amount
[**]	[**] Dollars (\$[**])
[**]	[**] Dollars (\$[**])
[**]	[**] Dollars (\$[**])

[**].

Beam shall notify Verve in writing within [**] following the achievement of each other milestone, and shall make the appropriate milestone payment within [**] after the achievement of such milestone. All milestone payments are payable only once per Licensed GalNAc Target under this Agreement for each GalNAc

Product to achieve such milestone. For purposes of this Section 9.2, one (1) Licensed Product or GalNAc Product, as the case may be, that [**] for multiple Indications, multiple patient populations or multiple dosage forms shall be deemed to be a single Licensed Product or GalNAc Product, as the case may be.

9.3 Net Sales Milestones.

9.3.1 Subject to Section 9.3.2, on a Licensed Product-by-Licensed Product basis, Verve will pay Beam the following one-time payments when aggregate Net Sales of a Licensed Product that is not a Collaboration Product in a Calendar Year in the Territory first reach the respective thresholds indicated below:

Calendar Year Territory-Wide Net Sales for a Licensed Product that is not a Collaboration Product	Net Sales Milestone
Over [**] U.S. Dollars (\$[**])	[**] U.S. Dollars (\$[**])
Over [**] U.S. Dollars (\$[**])	[**] U.S. Dollars (\$[**])

9.3.2 Notwithstanding Section 9.3.1, on a Licensed Product-by-Licensed Product basis, with respect to any Licensed Product that is a Collaboration Product, Verve will pay Beam the following one-time payments when aggregate Net Sales of such Licensed Product outside the Collaboration Territory first reach the respective thresholds indicated below:

Calendar Year Net Sales for a Licensed Product that is a Collaboration Product Outside the Collaboration Territory	Net Sales Milestone
Over [**] U.S. Dollars (\$[**])	[**] U.S. Dollars (\$[**])
Over [**] U.S. Dollars (\$[**])	[**] U.S. Dollars (\$[**])

9.3.3 Verve will make any Net Sales threshold milestone payment payable with respect to a Calendar Year within [**] after the end of the applicable Calendar Year. The Net Sales threshold milestone payments set forth above are payable only once on the first achievement by each Licensed Product of the relevant threshold. No amounts shall be due under this Agreement for subsequent or repeated achievements of any milestone by the same Licensed Product. If more than one Net Sales threshold milestone is achieved in the same Calendar Year, Verve will pay to Beam all Net Sales threshold milestone payments achieved in such Calendar Year in accordance with this Section 9.3.3.

9.4 Royalties.

9.4.1 Royalties to Beam for Licensed Products.

(a) Subject to the provisions of <u>Sections 9.4.1(c)</u> and <u>9.4.1(d)</u>, Verve will pay Beam royalties on a tiered marginal royalty rate basis as set forth below based on the annual aggregate Territory-wide Net Sales resulting from

the sale of each Licensed Product that is not a Collaboration Product, on a Licensed Product-by-Licensed Product basis, during each Calendar Year of the applicable Royalty Term for each such Licensed Product.

Net Sales of a Licensed Product that is not a Collaboration Product	Marginal Royalty Rate (% of Calendar Year Net Sales for such Licensed Product in the Territory)
Annual Net Sales up to [**] Dollars (\$[**])	[**]%
Annual Net Sales including and above [**] Dollars (\$[**]), up to [**] Dollars (\$[**])	[**]%
Annual Net Sales including and above [**] Dollars (\$[**])	[**]%

Each marginal royalty rate set forth in the table above will apply only to that portion of the Net Sales of a given Licensed Product in the Territory during a given Calendar Year that falls within the indicated range.

(b) Subject to the provisions of <u>Sections 9.4.1(c)</u> and <u>9.4.1(d)</u>, Verve will pay Beam royalties on a tiered marginal royalty rate basis as set forth below based on the annual aggregate Net Sales outside of the Collaboration Territory resulting from the sale of each Licensed Product that is a Collaboration Product, on a Licensed Product-by-Licensed Product basis, during each Calendar Year of the applicable Royalty Term for each such Licensed Product.

Net Sales of a Licensed Product that is a Collaboration Product Outside of the Collaboration Territory	Marginal Royalty Rate (% of Calendar Year Net Sales for such Licensed Product outside the Collaboration Territory)
Annual Net Sales up to [**] Dollars (\$[**]).	[**]%
Annual Net Sales including and above [**] Dollars (\$[**]), up to [**] Dollars (\$[**])	[**]%
Annual Net Sales including and above [**] Dollars (\$[**])	[**]%

Each marginal royalty rate set forth in the table above will apply only to that portion of the Net Sales of a given Licensed Product in the applicable countries outside the Collaboration Territory during a given Calendar Year that falls within the indicated range.

(c) During time periods when the Royalty Term is only in effect in a given country for a given Licensed Product due to clause (c) of Section 1.170.1, then the royalty rate provided for such Licensed Product in such country shall be reduced by [**] percent ([**]%) from that set forth in Section 9.4.1(a) or 9.4.1(b), as applicable, above for such portions of the Royalty Term for such Licensed Product in such country. During time periods when the Royalty Term is only in effect in a given country for a given

Licensed Product due to the applicable Licensed Product being Covered by a Valid Claim of the [**] in such country, then the royalty rate provided for such Licensed Product in such country shall be reduced by [**] percent ([**]%) from that set forth in Section 9.4.1(a) or 9.4.1(b), as applicable, above for such portions of the Royalty Term for such Licensed Product in such country.

(d) On a Licensed Product-by-Licensed Product basis, if Verve is legally required by a future court order, settlement agreement, contract, or other legally binding written commitment to make payments to a Third Party for a license under or the use of Patent Rights held by such Third Party that [**], then Verve may offset [**] percent ([**]%) of any running royalty payments on net sales actually paid by Verve to such Third Party under such Third Party license with respect to such patent application(s) or patent(s) with respect to sales of such Licensed Product against the running royalty payments that are due to Beam with respect to Net Sales of such Licensed Product in such country under Section 9.4.1(a) or 9.4.1(b), as applicable; provided that, in no event, shall (a) the running royalty payments to Beam with respect to such any Licensed Products be reduced, after the application of any reduction in Section 9.4.1(c) and this Section 9.4.1(d), by more than [**] percent ([**]%) of the amount otherwise due under Section 9.4.1(a) or 9.4.1(b), as applicable, and (b) with respect to royalties paid to the Third Party solely on the basis of claims of pending patent applications of the Third Party (and no issued patent claim of the Third Party Covers the applicable Licensed Product), such amounts shall only be offsettable in accordance with this Section 9.4.1(d) if the Covering pending claim of the Third Party's pending application would meet the definition of Valid Claim set forth in this Agreement were such pending claim within the Patent Rights as of the Restatement Effective Date.

9.4.2 Royalties to Verve for GalNAc Products (other than [**] Products).

- (a) Subject to the provisions of Section 9.4.2(b) and 9.4.2(c), Beam will pay Verve royalties at the rate of [**] percent ([**]%) of the annual aggregate Territory-wide Net Sales resulting from the sale of each GalNAc Product that is not also a [**] Product, on a GalNAc Product-by-GalNAc Product basis, during each Calendar Year of the applicable Royalty Term for each such GalNAc Product.
- (b) During time periods when the Royalty Term is only in effect in a given country for a given GalNAc Product due to clause (c) of Section 1.170.2, as applicable, then the royalty rate provided for such GalNAc Product in such country shall be reduced by [**] percent ([**]%) from that set forth in Section 9.4.2(a), as applicable, above for such portions of the Royalty Term for such GalNAc Product in such country.

(c) On a GalNAc Product-by-GalNAc Product basis, if Beam is legally required by a future court order, settlement agreement, contract, or other legally binding written commitment to make payments to a Third Party for a license under or the use of Patent Rights held by such Third Party that [**], then Beam may offset [**] percent ([**]%) of any running royalty payments on net sales actually paid by Beam to such Third Party under such Third Party license with respect to such patent application(s) or patent(s) with respect to sales of such GalNAc Product against the running royalty payments that are due to Verve with respect to Net Sales of such GalNAc Product in such country under Section 9.4.2(a); provided that in no event shall (a) the running royalty payments to Verve with respect to such GalNAc Products be reduced, after the application of any reduction in <u>Section 9.4.2(b)</u> and this Section 9.4.2(c), by more than [**] percent ([**]%) of the amount otherwise due under Section 9.4.2(a) and (b) with respect to royalties paid to the Third Party solely on the basis of claims of pending patent applications of the Third Party (and no issued patent claim of the Third Party Covers the applicable GalNAc Product), such amounts shall only be offsettable in accordance with this Section 9.4.1(c) if the Covering pending claim of the Third Party's pending application would meet the definition of Valid Claim set forth in this Agreement were such pending claim within the Patent Rights as of the Restatement Effective Date.

9.5 Revenue and Cost Sharing in the Collaboration Territory; Reconciliation Payments.

- **General.** The terms and conditions of this Section 9.5 shall govern each Party's rights and obligations with respect to Shared Development Costs, Shared Commercialization Costs and Collaboration Territory Revenue, in each case relating to Collaboration Products. In the event of a conflict between Section 9.5.1(a) or 9.5.1(b), on one hand, and, on the other hand, any Schedules to this Agreement, the terms of Section 9.5.1(a) or 9.5.1(b) shall take precedence, govern and control.
 - (a) The Parties shall share all Shared Development Costs for (a) each Collaboration Product [**] of ANGPTL3 or PCSK9 incurred pursuant to this Agreement on the basis of [**] percent ([**]%) by Verve and [**] percent ([**]%) by Beam and (b) each Collaboration Product [**] incurred pursuant to this Agreement on the basis of sixty-five percent (65%) by Verve and thirty-five percent (35%) by Beam; provided, however, that in the event Beam exercises a Beam Opt-In Option upon receipt of an [**] for a Collaboration Product, Verve will be solely responsible for all of its own costs and all FTE Costs and out-of-pocket costs that are incurred as an expense in accordance with GAAP (including Third Party Payments) by Beam or any of its Affiliates in connection with all Development activities through the end of the Phase I Clinical Trial for such Collaboration Product, in accordance with Section 5.1 and the applicable Subsequent Development Plan.

- (i) **Development Budget for Collaboration Products**. Notwithstanding the foregoing, expenses charged by either Party as Shared Development Costs for an activity under a Subsequent Development Plan shall not exceed [**] percent ([**]%) of the amount included for the total itemized expenditure in the relevant then-current Development Budget for such activity, and any expenses in excess of such [**]% threshold shall be borne by the incurring Party except if the cause of the excess expenditures is outside the incurring Party's reasonable control, in which case the incurring Party shall, upon learning of the likelihood of the excess expenditure, promptly revise the Development Budget and submit it in writing, with an explanation of the variance and the reasons therefor, to the JDC. If the JDC recommends approval of the revised budget (the consent of each Party's representatives on the JDC not to be unreasonably withheld, delayed or conditioned) then such revised Development Budget shall be incorporated into the respective Subsequent Development Plan.
- (b) For each Collaboration Product [**] of ANGPTL3 or PCSK9, the Parties shall share all Shared Commercialization Costs for such Collaboration Product incurred pursuant to this Agreement, and Collaboration Territory Revenue for each such Collaboration Product in the Collaboration Territory on the basis of fifty percent (50%) by Verve and fifty percent (50%) by Beam. For each Collaboration Product [**], the Parties shall share all Shared Commercialization Costs for such Collaboration Product incurred pursuant to this Agreement, and Collaboration Territory Revenue for each such Collaboration Product in the Collaboration Territory on the basis of sixty-five percent (65%) by Verve and thirty-five percent (35%) by Beam. Notwithstanding the provisions of Section 9.5.1(a), Verve shall bear [**] percent ([**]%) of all Development costs and Commercialization costs for Products for which Beam has elected to exercise the Beam Opt-Out Option pursuant to Section 5.3, which costs are incurred by Verve following the applicable Opt-Out Date, subject to the last sentence of Section 5.3, and Beam shall bear [**] percent ([**]%) of all Development costs and Commercialization costs for Products for which Verve has elected to exercise the Verve Opt-Out Option pursuant to Section 5.4, which costs are incurred by Beam following the applicable Opt-Out Date, subject to the last sentence of Section 5.4. Expenses charged by either Party as Shared Commercialization Costs for an activity under a Commercialization Plan shall not exceed [**] percent ([**]%) of the amount included for the total itemized expenditure in the relevant then-current Commercialization Budget for such activity and any expenses in excess of such [**]% threshold shall be borne by the incurring Party except if the cause of the excess expenditures is outside the incurring Party's reasonable control (for example, due to cost increases resulting from the macroeconomic environment), in which case the incurring Party shall, upon learning of the likelihood of the excess

expenditure, promptly revise the Commercialization Budget and submit it in writing, with an explanation of the variance and the reasons therefor, to the JCC. If the JCC recommends approval of the revised budget (the consent of each Party's representatives on the JCC not to be unreasonably withheld, delayed or conditioned) then such revised Commercialization Budget shall be incorporated into the respective Commercialization Plan.

9.5.2 <u>Calculation and Payment</u>.

- (a) Following any exercise by Beam of the Beam Opt-In Option, within [**] after the end of each Calendar Quarter, each Party shall provide the other Party and the JCC and JDC, as applicable, with (i) a detailed, activity-based statement of its Shared Development Costs incurred in such Calendar Quarter, including, without limitation, an itemized breakdown of the calculation of FTE Costs included in the Shared Development Costs (each, a "Development Cost Report"), (ii) a detailed, activity-based statement of its Shared Commercialization Costs (each statement, together with the corresponding Development Cost Report, the "Cost Reports"), in each case to the extent incurred in such Calendar Quarter (or a good faith estimate of any portions thereof where actuals are not known as of such time), as well as details of any adjustments to be made to the amounts submitted in the previous Calendar Quarter in previous Cost Reports, in a format to be agreed upon by the JCC and JDC, as applicable.
- (b) Along with the Cost Reports, Verve shall provide Beam and the JCC with a report setting forth Verve's itemized Net Sales of each Collaboration Product in the Collaboration Territory during such Calendar Quarter.
- (c) Within [**] after the end of each Calendar Quarter, each Party will provide the other Party and the JSC with a written, non-binding, preliminary report that will set forth, in a format to be mutually agreed by the Parties not later than [**], such Party's good faith estimate of: (i) the amounts and information that will be set forward in such Party's Cost Reports for such Calendar Quarter; and (ii) in the case of Verve, the aggregate Net Sales of Collaboration Products in the Collaboration Territory and Collaboration Territory Revenue for such Calendar Quarter.
- (d) In addition to the preliminary reports to be provided by each Party in accordance with Section 9.5.2(c) above, within [**] after the end of each Calendar Quarter, Verve shall provide Beam and the JSC with a written report (the "Reconciliation Report") setting forth, in a format to be mutually agreed by the Parties not later than [**], the calculations of [**]. Any net payment owed from one Party to the other Party shall be paid within [**] following receipt of such reconciliation (i.e. within [**] after the end of the Calendar Quarter); provided that if a Party disputes an amount provided in such Reconciliation Report then such disputed

amount shall be reviewed by the JDC (with respect to Shared Development Costs) or JCC (with respect to Shared Commercialization Costs or Net Sales), as applicable, and any net payment owed with respect to the undisputed amounts shall be paid within such [**] period (and the disputed amount, if determined to be owed, shall be paid within [**] of resolution of the dispute). If requested by Verve or Beam, any invoices or other supporting documentation for any payments to a Third Party that individually exceed [**] Dollars (\$[**]) shall be promptly provided.

- **9.6 Sublicense Income**. Verve shall pay to Beam an amount equal to [**] percent ([**]%) of any Sublicense Income received by Verve or its Affiliates under sublicenses granted by Verve within [**] of the Restatement Effective Date. Verve shall notify Beam in writing within [**] after receiving any Sublicense Income, and Sublicense Income payments due under this Section 9.6 shall be paid within [**] of the receipt of such Sublicense Income. For clarity, this Section 9.6 does not limit Verve's obligations pursuant to Section 2.4.4.
- 9.7 Currency Exchange. All payments to be made by a Party under this Agreement shall be made in US dollars, by wire transfer, pursuant to the instructions of the Party receiving payment, as designated from time to time. To the extent Shared Development Costs or Shared Commercialization Costs are incurred in a currency other than US dollars, the applicable expense shall be converted into US dollars on a monthly basis using as a rate of exchange the average actual foreign currency exchange rate for the month in which the expense is incurred. Likewise, to the extent Licensed Products or Collaboration Products are sold in a currency other than US dollars, the amount received shall be converted into US dollars on a monthly basis using as a rate of exchange the average actual foreign currency exchange rate for the month in which the expense is incurred. All currency conversions shall be according to the exchange rates utilized by each Party in its own internal accounting system, consistently applied.

9.8 Record-Keeping and Audit.

9.8.1 Each Party and its Affiliates shall maintain complete and accurate books and records of account, in accordance with GAAP, of all transactions and other business activities under this Agreement, sufficient to confirm the accuracy of all reports furnished by a Party to the other Party under this Agreement, and all payments by a Party to the other Party under this Agreement. During the Term and for [**] after final payment has been made under this Agreement, upon reasonable written notice to a Party, but no more often than [**], such Party shall permit an independent certified public accountant of national standing designated by the other Party to audit such books and records of account of such Party in order to confirm the accuracy and completeness of all such reports and all such payments. The accounting firm shall disclose to the Party requesting the audit only whether the audited reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to the Party requesting the audit.

- 9.8.2 The Party requesting an audit shall bear all costs and expenses incurred in connection with any such audit; provided, however, that if any such audit correctly identifies any underpayments by the audited Party hereunder or overpayments by the auditing Party that are the fault of the audited Party hereunder in excess of [**] percent ([**]%) of the amount actually payable by such Party to the Party requesting the audit hereunder, or \$[**] US dollars, whichever is greater, then, in addition to paying the full amount of such underpayment or overpayment, the audited Party shall reimburse the other Party for all reasonable out-of-pocket costs and expenses incurred by such Party in connection with that audit.
- **9.8.3** Neither Party shall be required to maintain books and records for more than [**] following the end of the Calendar Year in which they were generated.
- **9.8.4** The Party requesting an audit shall treat all financial information subject to review under this <u>Section 9.8</u> in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the audited Party obligating it to retain all such information in confidence pursuant to such confidentiality agreement.

9.9 Income Tax Withholding.

- **YAT**. It is understood and agreed between the Parties that any payments made under this Agreement are exclusive of any value added or similar tax (VAT), which shall be added thereon as applicable. Where value added tax or similar tax is properly added to a payment made under this Agreement, the Party making the payment will pay the amount of value added tax or similar tax only on receipt of a valid tax invoice issued in accordance with the Applicable Laws of the country in which the value added tax or similar tax is chargeable.
- **Withholding Taxes**. In the event any payments made pursuant to this Agreement become subject to withholding taxes under the laws or regulation of any jurisdiction, the Party making such payment shall deduct and withhold the amount of such taxes for the account of the payee to the extent required by Applicable Laws or regulations and such amounts payable to the payee shall be reduced by the amount of taxes deducted and withheld. Any such withholding taxes required under Applicable Laws or regulations to be paid or withheld shall be an expense of, and borne solely by, the payee.
- **Tax Cooperation**. To the extent that the Party making a payment is required to deduct and withhold taxes on any payments under this Agreement, the Party making such payment shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the payee an official tax certificate or other evidence of such withholding sufficient to enable the payee to claim such payments of taxes. The payee shall provide any tax forms to the Party making such payment that may be reasonably necessary in order for such Party not to withhold tax or to withhold tax at a reduced rate under

an applicable bilateral income tax treaty. The payee shall use reasonable efforts to provide any such tax forms to the Party making the payment at least [**] prior to the due date for any payments for which the payee desires that the Party making the payment apply a reduced withholding rate. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT.

- 9.9.4 Notwithstanding anything in this Agreement to the contrary, if an action (including but not limited to any assignment or sublicense of its rights or obligations under this Agreement, or any failure to comply with Applicable Laws or filing or record retention requirements) by a Party leads to the imposition of withholding tax liability or VAT on the other Party that would not have been imposed in the absence of such action or in an increase in such liability above the liability that would have been imposed in the absence of such action, such Party shall indemnify and hold harmless the other Party from any such additional or increased withholding tax liability or VAT (except to the extent that the other Party can reclaim it, provided that such other Party will be reimbursed for any reasonable out of pocket costs incurred in the reclaim).
- **9.10 Late Payments.** Any payments by a Party that are not being disputed in good faith by such Party and not paid on or before the date such payments are due under this Agreement will bear interest at the lower of (a) [**] percent ([**]%) [**] and (b) the maximum rate allowed by law. Interest will accrue beginning on the [**] day following the due date for payment and will be compounded [**]. Payment of such interest by the relevant Party shall not limit, in any way, the other Party's right to exercise any other remedies it may have as a consequence of any payment due but unpaid hereunder.
- 9.11 Third Party Financing Transaction. Should either Party wish to enter into any royalty financing, monetization or similar transaction in relation to this Agreement (whether through the issue of debt or equity or the grant of a security interest in this Agreement) with a Third Party, such Party shall notify the other Party of any requested amendments to the terms of this Agreement as reasonably necessary to consummate such transaction. Following such notice, the Parties shall discuss in good faith and reasonably agree in good faith within [**] to appropriate modifications, provided that such terms do not (a) reduce any financial consideration owed to such other Party or would otherwise materially and adversely limit its rights to Licensed Products, or increase its obligations, under this Agreement, (b) require such other Party to share with any Third Party Confidential Information other than financial information and notices exchanged between the Parties under this Agreement that relate to the product(s) subject to such transaction (and provided that such Third Party is bound by confidentiality and non-use obligations substantially equivalent to those of this Agreement), or (c) provide any Third Party with the right to enforce any provision under this Agreement.
- **9.12 Licensed Products Directed towards Multiple Licensed Targets**. For clarity, the Parties agree and acknowledge that a Licensed Product may be directed towards more than one

Licensed Target (a "Multiplexed Licensed Product"), and that any such Multiplexed Licensed Product shall be subject to a single royalty as applicable under <u>Section 9.4.1</u>, but shall be considered for purposes of <u>Sections 9.2</u> and <u>9.3</u> as such number of Licensed Products as there are Licensed Targets towards which such Multiplexed Licensed Product is directed. By way of example, [**].

Article 10 CONFIDENTIALITY AND PUBLICATION

- 10.1 Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that the receiving Party (the "Receiving Party") shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential and proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which is disclosed to it by the other Party (the "Disclosing Party") or otherwise received or accessed by a Receiving Party in the course of performing its obligations or exercising its rights under this Agreement or the Original Agreement, including trade secrets, Know-How, inventions or discoveries, proprietary information, formulae, processes, techniques and information relating to a Party's past, present and future Commercialization, financial, and Development activities of any product or potential product or useful technology of the Disclosing Party and the pricing thereof (collectively, "Confidential Information"), except to the extent that it can be established by the Receiving Party that such Confidential Information:
 - 10.1.1 was in the lawful knowledge and possession of the Receiving Party prior to the time it was disclosed to, or learned by, the Receiving Party, or was otherwise developed independently by the Receiving Party, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the Receiving Party;
 - 10.1.2 was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;
 - 10.1.3 became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement; or
 - 10.1.4 was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others.

For clarity, with respect to intellectual property Controlled by Beam and disclosed to Verve, Beam shall be considered the Disclosing Party, with respect to intellectual property Controlled by Verve and Clinical Trial Data owned by Verve and disclosed to Beam, Verve shall be considered the Disclosing Party, and with respect to Joint Collaboration Technology, subject to Section 12.1.4, both Beam and Verve shall each be considered the Disclosing Party.

- 10.2 Authorized Disclosure. Except as expressly provided otherwise in this Agreement, a Receiving Party may use and disclose Confidential Information of the Disclosing Party as follows: (a) under appropriate confidentiality provisions similar to those in this Agreement, in connection with the performance of its obligations or exercise of rights granted or reserved in this Agreement (including the rights to Develop, Manufacture and Commercialize Products and to grant sublicenses as permitted hereunder); or (b) to the extent such disclosure is reasonably necessary in filing or prosecuting patent. copyright and trademark applications in accordance with this Agreement, prosecuting or defending litigation, complying with applicable governmental regulations, seeking and obtaining regulatory approval, conducting non-clinical activities or clinical trials, preparing and submitting INDs to Regulatory Authorities, or is otherwise required by Applicable Law or the rules of a recognized stock exchange or automated quotation system applicable to such Party; provided, however, that if a Receiving Party is required by Applicable Law to make any such disclosure of a Disclosing Party's Confidential Information it will, except where impracticable, give reasonable advance notice to the Disclosing Party of such disclosure requirement and, if requested by the Disclosing Party, cooperate with the Disclosing Party to secure confidential treatment of such Confidential Information required to be disclosed; or (c) in communication with existing or prospective investors, consultants, advisors, licensees or collaborators or others on a need to know basis, in each case that are not Competitors of the Disclosing Party and under appropriate confidentiality provisions substantially equivalent to those of this Agreement (except for the term of such obligations, which shall be customary for the particular disclosure) or (d) to the extent mutually agreed to in writing by the Parties.
- 10.3 Publications. Verve and Beam each acknowledge the other Party's interest in publishing the results of its research in order to obtain recognition within the scientific community and to advance the state of scientific knowledge. Each Party also recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade secret information. Consequently, except for disclosures permitted pursuant to Section 10.2, if either Party, its Affiliates, or their respective employee(s) wishes to make a publication or public presentation related to a Collaboration Product or Licensed Product or which otherwise may reasonably contain Confidential Information, of the other Party, such Party must first obtain approval by the JSC of the general subject matter of such proposed publication or presentation and thereafter shall deliver to such other Party a copy of the proposed written publication or an outline of any proposed oral disclosure at least [**] prior to submission for publication or presentation. The reviewing Party shall have the right (a) to require removal from the publication or presentation of such reviewing Party's Confidential Information or (b) to request a reasonable delay in publication or presentation in order to protect patentable information. If the reviewing Party requests a delay, the publishing Party shall delay submission or presentation for a period of [**] to enable patent applications protecting each Party's rights in such information to be filed in accordance with Section 12.2. Upon expiration of such [**], the publishing Party shall be free to proceed with the publication or presentation. If the reviewing Party requests modifications to the publication or presentation, the publishing or presenting Party shall edit such publication or presentation to prevent disclosure of Confidential Information, trade secret and proprietary business information of the reviewing Party prior to submission of the publication or presentation. Notwithstanding the foregoing, the Parties agree that (i)

study information and results must be posted to clinicaltrials.gov in accordance with statutory deadlines and (ii) such study results required to be posted pursuant to clause (i) of this <u>Section 10.3</u> will, following such posting, no longer constitute Confidential Information of either Party.

- 10.4 Press Releases; Disclosure of Agreement. The Parties shall discuss in good faith and reasonably cooperate in determining whether to issue a press release (jointly or separately) regarding the execution of this Agreement; provided that, as between the Parties, Beam shall control any press release to the extent discussing [**] and Verve shall control any press release to the extent discussing [**]. Without limiting the preceding sentence, neither Party shall issue or cause the publication of any press release or public announcement regarding the terms of this Agreement without the express prior approval of the other Party other than as required by Applicable Law or the rules of any stock exchange, provided that if any such publication, press release or public announcement is required by Applicable Law, the Party obligated to make such publication, press release or public announcement shall, if practicable, notify the other Party in advance thereof and reasonably consider any timely comments from such other Party, including any reasonable request to limit such publication, press release or public announcement. Notwithstanding anything to the contrary in this Agreement, each Party may disclose this Agreement, as well as redacted versions of any Third Party Agreements provided to such Party, on a reasonable need-to-know basis to actual and potential investors, acquirers, sublicensees and collaborators under reasonable conditions of confidentiality, including, in the case of the applicable Third Party Agreements, confidentiality obligations imposed under such Third Party Agreements.
- **10.5 Use of Names**. Neither Party shall use the name, symbol, trademark, trade name or logo of the other Party or its Affiliates in any press release, publication or other form of public disclosure without the prior written consent of the other Party in each, except for those disclosures for which consent has already been obtained, including as authorized in Section 2.3.
- **10.6 Termination of Prior Agreement**. This Agreement supersedes and replaces the Mutual Confidential Disclosure Agreement by and between the Parties dated as of [**] (the "Existing Confidentiality Agreement"). All information exchanged between the Parties under the Existing Confidentiality Agreement shall be deemed Confidential Information of the respective Disclosing Party hereunder and shall be so subject to the terms of this Agreement.
- **10.7 Remedies**. Each Party shall be entitled to seek, in addition to any other right or remedy it may have, at Applicable Law or in equity, a temporary injunction, without the posting of any bond or other security, enjoining or restraining the other Party from any violation or threatened violation of this <u>Article 10</u>.

Article 11 REPRESENTATIONS, WARRANTIES AND COVENANTS

11.1 Representations and Warranties of Each Party. Each Party represents and warrants to the other Party that as of the Restatement Effective Date:

- 11.1.1 it has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder;
- 11.1.2 this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material Applicable Law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and
- 11.1.3 it is licensed, registered, or qualified under Applicable Law, regulations, policies, and administrative requirements to do business.
- **11.2 Verve Representations, Warranties and Covenants**. Verve represents and warrants to Beam as of the Restatement Effective Date, and, with respect to Sections 11.2.10, 11.2.14, 11.2.15 and 11.2.16, covenants during the Term, that:
 - 11.2.1 Verve has disclosed to Beam (a) all Patent Rights within the Verve Base Editing Technology, (b) all Patent Rights within the Verve [**] Technology, Verve GalNAc Technology, and Verve [**] Technology and (c) all material data generated by Verve in relation to [**], in each case (clauses (a), (b) and (c)) in existence as of the Restatement Effective Date;
 - during the Original Agreement Term, Verve has not performed any material activities to Develop any product that binds to or modulates [**] and has not generated any material data regarding the editing of [**], except as set forth in Schedule 11.2.2;
 - the Patent Rights listed on <u>Schedule 1.205</u> are all the Verve GalNAc Patent Rights in existence as of the Restatement Effective Date, the Patent Rights listed on <u>Schedule 1.211</u> are all the Verve Lipid Patent Rights in existence as of the Restatement Effective Date and the Patent Rights listed on <u>Schedule 1.194</u> are all the [**] Product-Specific Patent Rights in existence as of the Restatement Effective Date;
 - the information, documents and materials furnished to Beam in connection with this Agreement, do not, taken as a whole, (a) contain any untrue statement of a material fact or (b) omit to state any material fact necessary to make the statements or facts contained therein, in light of the circumstances under which they were made, not misleading;
 - to Verve's knowledge, the Patent Rights to be licensed to Beam under <u>Sections 2.1.2</u> through <u>2.1.6</u> and <u>2.1.8</u>, have been properly maintained and are not invalid or unenforceable, in whole or in part;
 - 11.2.6 Verve is the sole and exclusive owner of, or has Control via a license to, the Know-How and Patent Rights licensed to Beam under <u>Sections 2.1.2</u> through <u>2.1.6</u> and <u>2.1.8</u>;

- 11.2.7 Verve has not granted any right or license to any Third Party relating to any of the Patent Rights within the Verve Base Editing Technology and, for Patent Rights Controlled by Verve other than those Patent Rights within the Verve Base Editing Technology, Verve has not granted any right or license to any Third Party relating to any such Patent Rights that conflicts or interferes with any of the rights or licenses granted hereunder by Verve to Beam;
- 11.2.8 Verve has the right to grant the licenses to the Verve [**] Technology granted to Beam hereunder;
- there are no claims, judgments or settlements against or owed by Verve and, to the knowledge of Verve, no pending or threatened claims or litigation relating to the Patent Rights Controlled by Verve to be licensed to Beam under Sections 2.1.2 through 2.1.6 and 2.1.8;
- 11.2.10 Verve will not, and will cause its Affiliates not to incur or permit to exist, with respect to any Know-How or Patent Rights Controlled by Verve or its Affiliates (including the Joint Collaboration Technology) any lien, encumbrance, charge, security interest, mortgage, liability, assignment, grant of license or other binding obligation that is or would be inconsistent with or would diminish, derogate from or otherwise conflict with the licenses and other rights granted to Beam under this Agreement;
- the Third Party Agreements set forth on Schedule 1.188(b) are all of the agreements or arrangements between Third Parties and Verve or its Affiliates under which Verve or its Affiliates are granted rights to any intellectual property rights related to or useful for the Development, Commercialization, Manufacture or use of any Product or pursuant to which Beam would be subject to any obligations (including payment obligations) based upon the rights granted by Verve to Beam under this Agreement or the Development or Commercialization of a Product under this Agreement:
- 11.2.12 Verve has provided to Beam true and correct partially-redacted copies of all Third Party Agreements to which Verve or its Affiliate is a party in their current form (including any amendments thereto) (each, a "Verve Third Party Agreement"), which Verve Third Party Agreements are in full force and effect, and the redacted provisions do not materially relate to Beam's rights or obligations under this Agreement, including provisions related to the scope of the licenses granted to Beam under Sections 2.1.2 through 2.1.6 and 2.1.8 or the ownership of any Patent Rights invented or Know-How conceived, developed, generated or reduced to practice arising out of a Party's performance of its obligations under this Agreement during the Term;
- 11.2.13 Verve is not in material breach and, to its knowledge, none of the Third Parties who are party to a Verve Third Party Agreement are in material breach of the relevant Verve Third Party Agreement, Verve has not waived or allowed to lapse or terminate any of its rights under any Verve Third Party Agreements that would

- adversely affect the rights granted to Beam under this Agreement, and Verve has not received any notice of breach of such Verve Third Party Agreements;
- 11.2.14 Verve shall not amend any Third Party Agreement to which Verve or any of its Affiliates is a party in a manner that would adversely affect the rights or obligations of Beam under this Agreement without Beam's prior written consent;
- 11.2.15 Verve shall furnish Beam with copies of all notices received by Verve relating to any alleged breach or default by Verve under any Verve Third Party Agreement within [**] after Verve's receipt thereof. In the event that Verve does not resolve any such breach that is an undisputed breach to make one or more payments when due under the Verve Third Party Agreement, Verve shall notify Beam within a sufficient period of time before the expiration of the cure period for such breach under such Verve Third Party Agreement such that Beam, in its sole discretion, is able to cure or otherwise resolve such payment breach. If Beam makes any payments to a Third Party in connection with the cure or other resolution of such payment breach of Verve, then Beam may credit the amount of such payments against any amounts payable to Verve pursuant to this Agreement; and
- 11.2.16 Verve shall promptly (and in any event within [**] following receipt) furnish Beam with copies (which may be redacted as to provisions that do not materially relate to Beam's rights or obligations under this Agreement) of all amendments of the Verve Third Party Agreements solely to the extent material to Beam or its rights granted under this Agreement.
- **11.3 Beam Representations, Warranties and Covenants**. Beam represents and warrants to Verve as of the Restatement Effective Date, and, with respect to Sections 11.3.8, 11.3.9, 11.3.10, and 11.3.12, covenants during the Term, that:
 - 11.3.1 to Beam's knowledge, the Beam Base Editor Patent Rights and Beam C2C1 Patent Rights have been properly maintained and are not invalid or unenforceable, in whole or in part;
 - 11.3.2 Beam is the sole and exclusive owner of, or has Control via a license to, the Beam Base Editor Patent Rights and Beam C2C1 Patent Rights;
 - the Patent Rights listed on <u>Schedule 1.19</u> are all the Beam Base Editor Patent Rights in existence as of the Restatement Effective Date, the Patent Rights listed on <u>Schedule 1.22</u> are all the Beam C2C1 Patent Rights in existence as of the Restatement Effective Date and the Patent Rights listed on <u>Schedule 1.9</u> are all the Patent Rights in existence as of the Restatement Effective Date owned by Beam or its Affiliates that solely claim Know-How that relates solely to the Development, Manufacture, Commercialization or use of one or more Base Editor Products directed towards [**] (including the composition and formulation thereof), and no other products;
 - 11.3.4 Beam has not granted any right or license to any Third Party relating to any of the Beam Base Editor Patent Rights or Beam C2C1 Patent Rights that conflicts

or interferes with any of the rights or licenses granted hereunder with respect to the Beam Base Editor Patent Rights and Beam C2C1 Patent Rights;

- the Third Party Agreements set forth on <u>Schedule 1.188(a)</u> are all of the agreements or arrangements between Third Parties and Beam or its Affiliates under which Beam or its Affiliates are granted rights to any Beam Base Editor Technology or Beam C2C1 Technology or pursuant to which Verve would be subject to any obligations (including payment obligations) based upon the rights granted by Beam to Verve under this Agreement or the Development or Commercialization of a Product under this Agreement;
- Beam has provided to Verve true and correct partially-redacted copies of all Third Party Agreements to which Beam or its Affiliate is a party in their current form (including any amendments thereto) (each, a "Beam Third Party Agreement"), which Beam Third Party Agreements are in full force and effect, and the redacted provisions do not materially relate to Verve's rights or obligations under this Agreement, including provisions related to the scope of the licenses granted to Beam under the Beam Base Editor Patent Rights or Beam C2C1 Patent Rights or the ownership of any Patent Rights invented or Know-How conceived, developed, generated or reduced to practice arising out of a Party's performance of its obligations under this Agreement during the Term:
- 11.3.7 Beam is not in material breach and, to its knowledge, none of the Third Parties who are party to a Beam Third Party Agreement are in material breach of the relevant Beam Third Party Agreement, Beam has not waived or allowed to lapse or terminate any of its rights under any Beam Third Party Agreements that would adversely affect the rights granted to Verve under this Agreement, and Beam has not received any notice of breach of such Beam Third Party Agreements;
- 11.3.8 Beam shall not amend any Beam Third Party Agreement in a manner that would adversely affect the rights or obligations of Verve under this Agreement without Verve's prior written consent;
- Beam shall furnish Verve with copies of all notices received by Beam relating to any alleged breach or default by Beam under any Beam Third Party Agreement within [**] after Beam's receipt thereof. In the event that Beam does not resolve any such breach that is an undisputed breach of Beam's obligation to make one or more payments when due under the Beam Third Party Agreement, Beam shall notify Verve within a sufficient period of time before the expiration of the cure period for such breach under such Beam Third Party Agreement such that Verve, in its sole discretion, is able to cure or otherwise resolve such payment breach. If Verve makes any payments to a Third Party in connection with the cure or other resolution of such payment breach of Beam, then Verve may credit the amount of such payments against any royalties or other amounts payable to Beam pursuant to this Agreement;

- 11.3.10 Beam shall promptly (and in any event within [**] following receipt) furnish Verve with copies (which may be redacted as to provisions that do not materially relate to Verve's rights or obligations under this Agreement) of all amendments of the Beam Third Party Agreements, solely to the extent material to Verve or its rights granted under this Agreement;
- 11.3.11 there are no claims, judgments or settlements against or owed by Beam and, to the knowledge of Beam, no pending or threatened claims or litigation relating to the Beam Base Editor Technology or Beam C2C1 Technology; and
- 11.3.12 Beam will not, and will cause its Affiliates not to incur or permit to exist, with respect to any Beam Base Editor Technology, Beam C2C1 Technology or Joint Collaboration Technology, any lien, encumbrance, charge, security interest, mortgage, liability, assignment, grant of license or other binding obligation that is or would be inconsistent with or would diminish, derogate from or otherwise conflict with the licenses and other rights granted to Verve under this Agreement.
- **11.4 Acknowledgement**. The Parties acknowledge and agree that any obligations requiring the disclosure of Know-How or other information from one Party to the other Party pursuant to the Original Agreement (including Sections 12.1 and 12.2 thereof) are hereby deemed to have been fulfilled in full.

11.5 Covenants of Verve.

- 11.5.1 Verve hereby grants, and shall cause its Affiliates to grant, to Beam an exclusive (even as to Verve and its Affiliates), royalty-free, fully paid-up license under the data regarding the editing of [**] set forth on Schedule 11.2.2, with a right to grant and authorize the further grant through multiple tiers of sublicenses in accordance with this Agreement (including Section 2.2), solely to Develop, make, have made, use, offer for sale, sell, have sold, and import Terminated Target Products in the Field in the Territory, and, without prejudice to Beam's rights pursuant to Section 13.2, if Verve is determined to have generated data during the term of the Original Agreement regarding [**] (other than such data as set forth on Schedule 11.2.2), then (a) such additional data shall automatically be deemed to be included in the license granted pursuant to this Section 11.5, and (b) Verve shall disclose, and shall cause its Affiliates to disclose, to Beam any such additional data relating to each Terminated Target.
- **11.5.2** Verve shall [**].
- 11.6 Disclaimer. THE FOREGOING REPRESENTATIONS AND WARRANTIES OF EACH PARTY ARE IN LIEU OF ANY OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED.

11.7 Mutual Release. Each Party hereby forever generally and completely releases and discharges the other Party and its directors, officers, employees, affiliates, subsidiaries, agents and representatives, from any and all claims, liabilities, obligations and demands of every kind and nature, in law, equity or otherwise, known and unknown, suspected and unsuspected, disclosed and undisclosed, occurring prior to the Restatement Effective Date and arising out of or in any way related to the negotiation of this Agreement or any breach of Sections 2.5, 3.3, 3.4, 3.6, 3.11, 4.1.1 (other than the last sentence of such Section), 4.2, 4.3, 6.1, 6.2, 8.3, 13.1.2, 13.1.3 and 13.2 of the Original Agreement.

Article 12 INTELLECTUAL PROPERTY PROVISIONS

12.1 Ownership of Intellectual Property.

- **12.1.1** General. Inventorship shall be determined in accordance with United States patent laws.
- 12.1.2 <u>Beam Owned Intellectual Property.</u> Subject to the licenses granted to Verve under Section 2.1.1 and the rights retained by Beam under Section 2.1.10, the entire right, title and interest in and to the Beam Base Editor Technology, Beam C2C1 Technology and Beam Collaboration Technology shall be owned solely by Beam. As between Verve and Beam, all right, title and interest in and to other intellectual property including all Know-How, patentable or otherwise, conceived, developed, generated or reduced to practice solely by Beam or its Affiliates or other persons acting on behalf of Beam (excluding Verve) in the performance of this Agreement or the Original Agreement shall be owned by Beam.
- 12.1.3 <u>Verve Owned Intellectual Property</u>. Subject to the license granted to Beam under Sections 2.1.2 through 2.1.6 and 2.1.8, the entire right, title and interest in and to the Verve Collaboration Technology, Verve GalNAc Technology, Verve Lipid Technology and the Clinical Trial Data shall be owned solely by Verve. As between Verve and Beam, all right, title and interest in and to other intellectual property including all Know-How, patentable or otherwise, conceived, developed, generated or reduced to practice solely by Verve or its Affiliates or other persons acting on behalf of Verve (excluding Beam) in the performance of this Agreement or the Original Agreement shall be owned by Verve.

Subject to the rights set forth herein, Beam, on behalf of itself and its respective successors and assigns, hereby quitclaims and assigns to Verve, any right, title, and interest Beam may have in and to (a) Know-How to the extent conceived, developed, generated or reduced to practice by Verve or its Affiliates or other persons acting on Verve's behalf prior to the Restatement Effective Date in the performance of the Original Agreement and (b) all Patents Rights claiming such Know-How.

To the extent necessary to perfect, record, or maintain Verve's ownership in and to the Know-How and Patent Rights referred to in the immediately preceding

paragraph, Beam hereby irrevocably designates and appoints Verve and Verve's duly authorized officers and agents as Beam's agents and attorneys-in-fact to act for and on Beam's behalf and instead of Beam solely for the purpose of signing any document that may be necessary or desirable for obtaining, sustaining, or reissuing Verve's rights in such Know-How and Patent Rights, including Patent Rights in the United States and throughout the world, or for perfecting, recording, or maintaining the title of Verve, and Verve's successors and assigns, in and to such Know-How and Patent Rights in the United States and throughout the world. The foregoing is deemed a power coupled with an interest and is irrevocable.

- **Jointly Owned Intellectual Property**. Subject to the licenses granted to each Party and the rights retained by each Party under Section 2.1, (a) Joint Collaboration Technology shall be owned jointly by Verve and Beam and (b) each Party shall have the non-exclusive right to use Joint Collaboration Know-How, practice the inventions claimed by the Joint Collaboration Patent Rights, and grant licenses under its interest in Joint Collaboration Technology, as it deems appropriate without the consent of or any obligation to the other Party, including any duty to account. The Parties acknowledge that, as of the Restatement Effective Date, [**].
- **Disclosure of Patent Rights.** During the Term, each Party will disclose to the other Party all Patent Rights covering Collaboration Know-How that is conceived, developed, generated or reduced to practice solely or jointly by or on behalf of such Party or its Affiliates (including Subcontractors thereof) and that is licensed to such other Party pursuant to Section 2.1; provided that neither Party shall be required to disclose to the other Party [**].
- **Acknowledgement of [**]**. Subject to the terms and conditions of this Agreement and Verve's compliance therewith, and without limiting in any way Beam's rights and Verve's obligations under this Agreement, Beam hereby acknowledges that Verve has the [**].

12.2 Filing, Prosecution and Maintenance of Patent Rights.

- As between the Parties, subject to <u>Section 12.3.2</u>, Beam shall have the exclusive right to file, prosecute and maintain the Beam Base Editor Patent Rights, Beam Collaboration Patent Rights and Beam C2C1 Patent Rights. Subject to Beam's obligations under Third Party Agreements, Beam shall give Verve the opportunity to provide comments on and make requests of Beam concerning the prosecution and maintenance of the Beam Base Editor Patent Rights, Beam C2C1 Patent Rights, Beam Collaboration Patent Rights, and Beam shall consider such comments and requests in good faith; however, final decision-making authority with respect to the prosecution and maintenance of such Patent Rights shall vest in Beam.
- 12.2.2 If and to the extent permitted by the Third Party Agreements to which Beam is a Party, Verve shall have the first right to file, prosecute and maintain Verve

Product-Specific Patent Rights at Verve's cost and expense. Verve will keep Beam advised on the status of the preparation, filing, prosecution, and maintenance of all patent applications included within such Verve Product-Specific Patent Rights and the maintenance of any issued patents included within such Verve Product-Specific Patent Rights. Further, Verve will consult and reasonably cooperate with Beam with respect to the preparation, filing, prosecution and maintenance of Verve Product-Specific Patent Rights, including: (i) allowing Beam a reasonable opportunity and reasonable time to review and comment regarding relevant communications to, and drafts of any responses or other proposed filings by Verve before any applicable filings are submitted to, any relevant patent office or Governmental Authority and (ii) reflecting any reasonable comments offered by Beam in any final filings submitted by Verve to any relevant patent office or Governmental Authority. If Verve elects not to file a patent application included in the Verve Product-Specific Patent Rights in a country in the Territory or elects to cease the prosecution or maintenance of any Verve Product-Specific Patent Right, Verve will provide Beam with written notice immediately, but not less than [**] before any action is required, upon the decision to not file or continue the prosecution of such patent application or maintenance of such patent. In such event, Verve will permit Beam to file or continue prosecution or maintenance of any such Verve Product-Specific Patent Right in such country.

- As between the Parties, Verve shall have the exclusive right to file, prosecute and maintain the Patent Rights licensed by Verve to Beam pursuant to <u>Section 2.1</u>, provided that with respect to Patent Rights within the Verve Base Editing Technology, Verve shall give Beam the opportunity to provide comments on and make requests of Verve concerning the prosecution and maintenance of such Patent Rights and:
 - (a) Verve shall consider such comments and requests in good faith; however, final decision-making authority with respect to the prosecution and maintenance of such Patent Rights shall vest in Verve; and
 - (b) if Verve elects not to file a patent application included in the Verve Base Editing Technology in a country in the Territory or elects to cease the prosecution or maintenance of any such Patent Right, Verve will provide Beam with written notice immediately, but not less than [**] before any action is required, upon the decision to not file or continue the prosecution of such patent application or maintenance of such patent. In such event, to the extent Beam wishes to file or continue prosecution or maintenance of any such Patent Right in such country, Beam will so advise Verve within [**] of Verve's written notice to Beam, and the costs (including attorney fees) associated with any such prosecution and maintenance of any such Patent Rights would be paid by Beam.

12.2.4 [Intentionally Omitted.]

- 12.2.5 With respect to any Joint Collaboration Patent Right, the Party responsible for the filing, prosecution and maintenance of such Joint Collaboration Patent Right shall be decided between the Parties in good faith, such decision to take into account the subject matter of the patent right and to which Party such subject matter is most relevant.
- Each Party shall in good faith consider requests by the other Party to segregate claims of Patent Rights Controlled by the Party or its Affiliates (which may be related, e.g., as continuations or divisionals of one another) to facilitate prosecution and enforcement strategies of the requesting Party of Patent Rights specifically and solely directed to a Party's licensed products.

12.3 Verve Product Competitive Infringement

- 12.3.1 Each Party shall give to the other Party notice of (i) any infringement of Beam Base Editor Patent Rights, Beam C2C1 Patent Rights, Beam Collaboration Patent Rights, or Joint Collaboration Patent Rights to the extent (in the case of Joint Collaboration Patent Rights) related to Base Editors or the use of C2C1 in a base editor or nuclease product but only, in each case, if such Patent Right is not a Verve Product-Specific Patent Right, or (ii) any misappropriation or misuse of Beam Base Editor Know-How, Beam C2C1 Know-How, Beam Collaboration Know-How, or Joint Collaboration Know-How to the extent (in the case of Joint Collaboration Know-How) related to Base Editors or the use of C2C1 in a base editor or nuclease product but only, in each case, if such Know-How is not Verve Product-Specific Know-How, that may come to such Party's attention, which infringement or misappropriation is by a Third Party that is developing or commercializing a product that is competitive with a Licensed Product (a "Verve Product Competitive Infringement"). Beam shall have the sole right to initiate and prosecute such legal action at its own expense and in the name of Beam and, if requested by Beam in the name of Verve, or to control the defense of any declaratory judgment action relating to such Patent Rights or Know-How.
- 12.3.2 For any action to terminate any Verve Product Competitive Infringement, in the event that Beam is unable to initiate or prosecute such action solely in its own name, Verve will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for Beam to initiate litigation to prosecute and maintain such action. Each Party shall have the right to be represented by counsel of its own choice, at its own expense in any such action. In connection with any action related to a Verve Product Competitive Infringement, Verve and Beam will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Beam shall keep Verve informed of developments in any action or proceeding related to a Verve Product Competitive Infringement, including, to the extent permissible by Applicable Law, consultation on any settlement, the status of any settlement negotiations and the terms of any offer related thereto.

- 12.3.3 Any recovery applicable to Licensed Products obtained by Beam in connection with or as a result of any action related to a Verve Product Competitive Infringement contemplated by this <u>Section 12.3</u>, whether by settlement or otherwise, shall be shared in order as follows:
 - (a) Beam shall recoup all of its costs and expenses incurred in connection with the action, including any payments owed by Beam to a Third Party under any Third Party Agreement as a result of such action or recovery;
 - (b) Verve shall then, to the extent possible, recover its costs and expenses incurred in connection with the action, including any payments owed by Verve to a Third Party under any Third Party Agreement as a result of such action or recovery; and
 - (c) [**].

12.4 Verve Product-Specific Patent Competitive Infringement.

- Each Party shall give the other Party notice of (a) any infringement of Verve Product-Specific Patent Rights, or Joint Collaboration Patent Rights to the extent (in the case of Joint Collaboration Patent Rights) not related to Base Editors or the use of C2C1 in a base editor or nuclease product, or (b) any misappropriation or misuse of Verve Product-Specific Know-How or any Joint Collaboration Know-How to the extent (in the case of Joint Collaboration Know-How) not related to Base Editors or the use of C2C1 in a base editor or nuclease product, that may come to such Party's attention, which infringement or misappropriation is by a Third Party that is developing or commercializing a product that is competitive with a Licensed Product (an "Verve Product Specific Competitive Infringement"). Verve shall have the sole right to initiate and prosecute such legal action at its own expense and in the name of Verve and, if requested by Verve in the name of Beam, or to control the defense of any declaratory judgment action relating to such Patent Rights or Know-How. Each Party shall have the right to be represented by counsel of its own choice at its own expense.
- 12.4.2 For any action to terminate any Verve Product Specific Competitive Infringement, in the event that Verve is unable to initiate or prosecute such action solely in its own name, Beam will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for Verve to initiate litigation to prosecute and maintain such action. In connection with any action related to a Verve Product Specific Competitive Infringement, Verve and Beam will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Verve shall keep Beam informed of developments in any action or proceeding related to a Verve Product Specific Competitive Infringement, including, to the extent permissible by Applicable Law, consultation on any settlement, the status of any settlement negotiations and the terms of any offer related thereto.

- Any recovery obtained by Verve in connection with or as a result of any action contemplated by this <u>Section 12.4</u>, whether by settlement or otherwise, shall be shared in order as follows:
 - (a) Verve shall recoup all of its costs and expenses incurred in connection with the action, including any payments owed by Verve to a Third Party under any Third Party Agreement as a result of such action or recovery;
 - (b) Beam shall, to the extent possible, recover its costs and expenses incurred in connection with the action, including any payments owed by Beam to a Third Party under any Third Party Agreement as a result of such action or recovery; and
 - (c) [**]<u>.</u>
- 12.5 [**] Product Competitive Infringement. Beam shall have the sole right, at its own expense, to initiate and prosecute any legal action against (a) any infringement of [**] Product-Specific Patent Rights, or (b) any misappropriation or misuse of [**] Product-Specific Know-How, and to control the defense of any declaratory judgment action relating to such Patent Rights or Know-How.

12.6 Verve IP Infringement.

- 12.6.1 Each Party shall give to the other Party notice of (a) any infringement by a Third Party of Patent Rights within the Verve Base Editing Technology, Verve GalNAc Patent Rights, Verve Lipid Patent Rights, Verve [**] Patent Rights or Patent Rights within the Verve [**] Technology (but, for clarity, excluding [**] Product-Specific Patent Rights, Beam Product-Specific Patent Rights and Joint Collaboration Patent Rights), or (b) any misappropriation or misuse by a Third Party of Know-How within the Verve Base Editing Technology, Verve GalNAc Know-How, Verve Lipid Know-How, Verve [**] Know-How or Know-How within the Verve [**] Technology (but, for clarity, excluding [**] Product-Specific Know-How, Beam Product-Specific Know-How and Joint Collaboration Know-How), that may come to such Party's attention (a "Verve IP Infringement"). Verve shall have the sole right to initiate and prosecute such legal action at its own expense and in the name of Verve and, if requested by Verve in the name of Beam, or to control the defense of any declaratory judgment action relating to such Patent Rights or Know-How (provided that the Parties' rights under this Section 12.6 with respect to Patent Rights within the Verve [**] Technology are limited to the extent of Verve's rights under the Verve-[**] Agreement).
- 12.6.2 For any action to terminate any Verve IP Infringement, in the event that Verve is unable to initiate or prosecute such action solely in its own name, Beam will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for Verve to initiate litigation to prosecute and maintain such action. Each Party shall have the right to be represented by counsel of its

own choice, at its own expense in any such action. In connection with any action related to a Verve IP Infringement, Verve and Beam will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Verve shall keep Beam informed of developments in any action or proceeding related to a Verve IP Infringement, including, to the extent permissible by Applicable Law, consultation on any settlement, the status of any settlement negotiations and the terms of any offer related thereto.

- 12.6.3 Any recovery applicable to a Verve IP Infringement contemplated by this <u>Section 12.6</u>, whether by settlement or otherwise, shall be shared in order as follows:
 - (a) Verve shall recoup all of its costs and expenses incurred in connection with the action, including any payments owed by Verve to a Third Party under any Third Party Agreement as a result of such action or recovery;
 - (b) Beam shall then, to the extent possible, recover its costs and expenses incurred in connection with the action, including any payments owed by Beam to a Third Party under any Third Party Agreement as a result of such action or recovery; and
 - (c) [**].

12.7 Beam Product Specific Competitive Infringement.

- Each Party shall give the other Party notice of (a) any infringement of Beam Product-Specific Patent Rights, or (b) any misappropriation or misuse of Beam Product-Specific Know-How, that may come to such Party's attention, which infringement or misappropriation is by a Third Party that is developing or commercializing a product that is competitive with a GalNAc Product or Lipid Technology Product (a "Beam Product Specific Competitive Infringement"). Beam shall have the sole right to initiate and prosecute such legal action at its own expense and in the name of Beam and if requested by Beam in the name of Verve, or to control the defense of any declaratory judgment action relating to such Patent Rights or Know-How. Each Party shall have the right to be represented by counsel of its own choice at its own expense.
- 12.7.2 For any action to terminate any Beam Product Specific Competitive Infringement, in the event that Beam is unable to initiate or prosecute such action solely in its own name, Verve will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for Beam to initiate litigation to prosecute and maintain such action. In connection with any action related to a Beam Product Specific Competitive Infringement, Verve and Beam will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Beam shall keep Verve informed of developments in any action or proceeding related to a Beam Product Specific Competitive Infringement, including, to the extent permissible by Applicable

Law, consultation on any settlement, the status of any settlement negotiations and the terms of any offer related thereto.

- Any recovery obtained by Beam in connection with or as a result of any action contemplated by this <u>Section 12.7</u>, whether by settlement or otherwise, shall be shared in order as follows:
 - (a) Beam shall recoup all of its costs and expenses incurred in connection with the action, including any payments owed by Beam to a Third Party under any Third Party Agreement as a result of such action or recovery;
 - (b) Verve shall, to the extent possible, recover its costs and expenses incurred in connection with the action, including any payments owed by Verve to a Third Party under any Third Party Agreement as a result of such action or recovery; and
 - (c) [**].
- 12.8 Enforcement and Defense of Other Patent Rights and Know-How. As between the Parties, except as provided under Sections 12.2 through Section 12.7, Verve shall have the exclusive right to initiate and prosecute any legal action to stop the misappropriation or misuse of any Know-How and the infringement of any Patent Rights, in each case licensed by Verve to Beam under Section 2.1, and defend any declaratory judgment action relating to such Patent Rights or Know-How. Subject to Verve's obligations under Third Party Agreements, Verve shall give Beam the opportunity to provide comments on and make requests of Verve concerning the enforcement and defense of such Patent Rights and Know-How, and Verve shall consider such comments and requests in good faith; however, final decision-making authority with respect to the enforcement and defense of such Patent Rights and Know-How shall vest in Verve, provided that in no event may Verve settle any such enforcement or defense claim in a manner that would limit the rights of Beam or impose any obligation on Beam, in each case, without Beam's prior written consent, which consent will not be unreasonably withheld, delayed, or conditioned.
- **12.9 Patent Term Restoration**. The Parties agree to cooperate and to take reasonable actions to maximize the protections available under the safe harbor provisions of 35 U.S.C. 103(c) for US patents and patent applications. The Parties shall cooperate with each other, including without limitation to provide necessary information and assistance as the other Party may reasonably request, in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Beam Base Editor Patent Rights, Beam C2C1 Patent Rights, Beam Collaboration Patent Rights, Verve Collaboration Patent Rights, Verve [**] Patent Rights, Verve GalNAc Patent Rights, Verve Lipid Patent Rights, [**] Product-Specific Patent Rights, other Patent Rights licensed by Verve or its Affiliate under this Agreement, or Joint Collaboration Patent Rights.
- 12.10 Trademarks and Corporate Logos.
 - **12.10.1 In the Collaboration Territory**.

- (a) Verve shall be responsible for developing a list of potential trademarks to be used to identify the Collaboration Products in the Collaboration Territory. From Verve's initial list, the JSC shall ultimately be responsible for the selection of the actual trademarks used to identify the Collaboration Products in the Collaboration Territory, and all trademarks, logos, taglines, trade dress, domain names or indicia of origin for use in connection with the sale or marketing of Collaboration Products in the Collaboration Territory (the "Collaboration Marks"). Verve shall be responsible for any associated creation, searching, clearance, filing, registration, and maintenance of the Collaboration Marks, and all expenses associated therewith shall be treated as Shared Commercialization Costs to the extent included in the Commercialization Budget for the applicable Collaboration Product. Verve shall keep Beam reasonably advised of the status of the actual and prospective trademarks filings and, upon Beam's request, shall provide advance copies of any substantive papers related to the filing, prosecution and maintenance of such filings. All uses of the proposed major promotional activities using Collaboration Marks and, upon request of the JSC, other representative samples of proposed use of the Collaboration Marks, shall be reviewed by the JSC prior to first public display and shall comply with all Applicable Laws (including, without limitation, those Applicable Laws and regulations particularly applying to the proper use and designation of trademarks in the applicable countries of the Collaboration Territory). Verve shall own all Collaboration Marks (including associated goodwill) and copyrights created in connection with the marketing of the Products in the Collaboration Territory.
- (b) With respect to those Collaboration Products for which Beam exercises its right to Co-Promote in the Collaboration Territory as set forth in Article 5, each Party shall provide to the other notice of any infringement or challenge to the Collaboration Marks. Verve and Beam shall thereafter consult and cooperate fully to determine a course of action, including but not limited to the commencement of legal action by either or both Verve and Beam. However, Verve, upon notice to Beam, shall have the first right to initiate and prosecute such legal action at its own expense and in the name of Verve and, if requested by Verve, in the name of Beam or to control the defense of any challenge relating to the Collaboration Marks. Verve shall promptly inform Beam if it elects not to exercise such first right and Beam shall, at its own expense, thereafter have the right to either initiate and prosecute such action or defend such action in the name of Beam and if requested by Beam in the name of Verve. Any recovery obtained by either or both Verve and Beam in connection with or as a result of any action contemplated by this Section 12.10, whether by settlement or otherwise, shall be shared in order as follows: (i) the Party which initiated and prosecuted the action shall recoup all of its costs and expenses incurred in connection with the action; (ii) the other Party shall then, to the extent possible, recover its costs and expenses incurred in

connection with the action; and (iii) the amount of any recovery remaining shall then be allocated equally between the Parties. In connection with any action, Verve and Beam will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Each Party shall keep the other informed of developments in any action or proceeding, including, to the extent permissible by Applicable Law, consultation on and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto. Each Party shall have the right to be represented by counsel of its own choice, at its expense.

- 12.10.2 <u>Use of Trademarks of the Other Party</u>. Neither Party shall, without the other Party's prior written consent, use any trademarks or house marks of the other Party (including the other Party's corporate name, and, in the case of Beam, any Collaboration Marks), or marks confusingly similar thereto, in connection with such Party's marketing or promotion of Products under this Agreement, except as expressly permitted pursuant to Section 2.3 or as may be expressly agreed to by the Parties and except to the extent required to comply with Applicable Laws.
- **12.10.3** Notices. To the extent a Party has obligations of notice to the other Party under this Agreement or the Original Agreement, it is understood and agreed by the Parties that any such notices are subject to a Party's confidentiality obligations to Third Parties and Affiliates.

Article 13 INDEMNIFICATION

- 13.1 General Indemnification by Beam. Beam shall indemnify and hold harmless Verve, its Affiliates and their respective directors, officers, employees and agents (collectively, the "Verve Indemnified Parties"), from, against and in respect of any and all liabilities, losses, costs (including costs of investigation and defense), damages, fines, penalties, government orders, taxes, expenses or amounts paid in settlement (in each case, including reasonable attorneys' and experts fees and expenses), in each case to the extent resulting from any Action brought by a Third Party (collectively, "Losses"), to the extent such Losses are incurred or suffered by the Verve Indemnified Parties or any of them as a result of, arising out of or directly or indirectly relating to: [**].
- **13.2 General Indemnification by Verve**. Verve shall indemnify and hold harmless Beam, its Affiliates and their respective directors, officers, employees and agents (collectively, the "**Beam Indemnified Parties**"), from, against and in respect of any and all Losses to the extent such Losses are incurred or suffered by the Beam Indemnified Parties or any of them as a result of, arising out of or directly or indirectly relating to: [**].
- **13.3 Products Liability Claims.** Notwithstanding anything express or implied to the contrary herein, including <u>Sections 13.1</u> and <u>13.2</u> hereof, in the event that there is a Third Party products liability claim for death, bodily injury or property damage suffered by such Third Party from or in connection with any Collaboration Product, then the liability, claims, damage, loss, or expense (including reasonable attorneys' fees) related to such claim

against either Party shall be shared by the Parties in the following allocation: (a) Verve shall bear [**] percent ([**]%) and Beam shall bear [**] percent ([**]%) of such related liability, claims, damage, loss and expense for Collaboration Products directed towards ANGPTL3 or PCSK9 and (b) Verve shall bear sixty-five percent (65%) and Beam shall bear thirty-five percent (35%) of such related liability, claims, damage, loss and expense for Collaboration Products directed towards [**]; provided in each case (clauses (a) and (b)) that in the event such death, bodily injury or property damage giving rise to a Third Party product liability claim is proximately caused by the negligence or willful misconduct, violation of Applicable Law or breach of the terms and conditions of this Agreement or the Original Agreement by a Party, its Affiliates or their respective directors, officers, employees or agents, this Section 13.3 shall not apply and Sections 13.1 and 13.2 will apply to the extent relevant. The Parties shall follow the procedures set forth in Section 13.4 and, solely for purposes of determining the procedure for the defense of such claim, Verve shall be deemed to be the Indemnifying Party under Section 13.4.

13.4 Claims for Indemnification.

- A Person entitled to indemnification under this <u>Article 13</u> (an "**Indemnified Party**") shall give prompt written notification to the Party from whom indemnification is sought (the "**Indemnifying Party**") of the commencement of any Third Party Action for which indemnification may be sought or, if earlier, upon the assertion of any such Action by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third Party Action as provided in this <u>Section 13.4.1</u> shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give notice).
- 13.4.2 Within [**] after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Action using counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense.
- 13.4.3 The Party not controlling such defense may participate therein at its own expense; <u>provided</u> that if the Indemnifying Party assumes control of such defense and the Indemnified Party reasonably concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such action, suit, proceeding or claim, the Indemnifying Party shall be responsible for the reasonable fees and expenses of counsel to the Indemnified Party solely in connection therewith; <u>provided further</u>, <u>however</u>, that in no event shall the Indemnifying Party be responsible for the fees and expenses of more than one counsel in any one jurisdiction for all Indemnified Parties.
- 13.4.4 The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto.

- 13.4.5 The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party without the prior written consent of the Indemnified Party.
- 13.5 Disclaimer of Liability. IN NO EVENT SHALL ANY PARTY OR ANY OF ITS RESPECTIVE AFFILIATES BE LIABLE UNDER THIS AGREEMENT OR THE ORIGINAL AGREEMENT FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES SUFFERED BY BEAM, VERVE OR ANY OF THEIR RESPECTIVE AFFILIATES IN CONNECTION WITH THIS AGREEMENT OR THE ORIGINAL AGREEMENT WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUE; PROVIDED THAT THIS SECTION SHALL NOT RELIEVE EITHER PARTY FROM ITS INDEMNIFICATION OBLIGATIONS UNDER THIS AGREEMENT OR FROM ITS LIABILITY FOR ANY DAMAGES BASED UPON SUCH PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 10, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

Article 14 TERM AND TERMINATION

- **14.1 Term**. The term of this Agreement (the "**Term**") will commence on the Restatement Effective Date and extend, unless this Agreement is terminated earlier in accordance with this <u>Article 14</u>, until the last to expire of any Royalty Term for any product in the Territory. Following expiration of the Royalty Term for any product in a given country, no further royalties will be payable in respect of sales of such product, as applicable, in such country and, thereafter the license granted to Beam under <u>Section 2.1.3</u> or to Verve under <u>Section 2.1.1</u>, as applicable, with respect to such Product in such country will automatically become fully paid-up, perpetual, irrevocable and royalty-free.
- 14.2 At-Will Termination by Verve. Notwithstanding anything contained herein to the contrary, Verve may terminate this Agreement as to any Licensed Product or Nuclease Product by ninety (90) days' prior written notice to Beam at its sole discretion; provided that (a) with respect to a Licensed Product or Nuclease Product other than Licensed Products directed towards [**], Verve may not submit a notice of termination under this Section 14.2 unless and until Beam has either (i) submitted a written notice to Verve under this Agreement that it does not wish to exercise any Beam Opt-In Option with respect to such Product or (ii) not exercised the Beam Opt-In Option with respect to such Product in the relevant [**] period set forth in Section 5.1 and no longer has the right to so exercise under this Agreement, and (b) Verve may not terminate this Agreement pursuant to this Section 14.2 with respect to any Collaboration Product.
- **14.3 At-Will Termination by Beam**. Notwithstanding anything contained herein to the contrary, Beam may terminate this Agreement as to any GalNAc Product, Lipid

Technology Product, or [**] Product by ninety (90) days' prior written notice to Verve at its sole discretion.

- **14.4 Termination for Cause**. This Agreement may be terminated at any time during the Term:
 - 14.4.1 upon written notice by either Party if the other Party is in breach of its material obligations under this Agreement and has not cured such breach within [**] after notice requesting cure of the breach; provided, however, that (a): in the event of a good faith dispute with respect to the existence of a material breach, the [**] cure period shall be tolled until such time as the dispute is resolved pursuant to Section 15.7; and (b) if, in the case of breach of this Agreement by Verve, such breach relates solely to compliance with Verve's obligations under the last sentence of Section 4.1.2, then such termination will only apply with respect to the termination of [**] as a Licensed Target; or
 - by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [**] after the filing thereof.
- 14.5 Termination for Patent Challenge. If the applicable Licensee or any of its Affiliates or sublicensees directly or indirectly brings, assumes or participates in, or knowingly, willfully or recklessly assists in bringing a Patent Challenge, then the following shall apply: (a) in the case of Beam as the Licensor, Beam may terminate this Agreement in its entirety immediately upon written notice to Verve; or (b) in the case of Verve as the Licensor, Verve may terminate the license granted to Beam pursuant to Sections 2.1.2 through 2.1.8 immediately upon written notice to Beam. For the avoidance of doubt, any participation by the Licensee, any of its Affiliates or sublicensees or its or their employees in any claim. challenge or proceeding that the Licensee, such Affiliates or sublicensees or such employees are required to participate in pursuant to a subpoena or court order or participates in a proceeding that is initiated by a patent office and not at the instigation of the Licensee, such Affiliates or sublicensees or such employees shall not constitute a Patent Challenge under this Section 14.5 and shall not give rise to Licensor's right to terminate any license hereunder. Notwithstanding anything to the contrary in this Agreement but only to the extent permitted by and consistent with the relevant Third Party Agreement (if any) under which the Challenged Patent Right is sublicensed to the Licensee, the Licensor shall not be entitled to exercise its termination rights pursuant to this Section 14.5 based upon any Patent Challenge by a sublicensee of the Licensee, if such Patent Challenge has been withdrawn or the Licensee has terminated such sublicense within [**] of the date on which the Licensor notifies the Licensee of its intent to exercise its termination rights pursuant to this Section 14.5.

14.6 Effects of Termination.

14.6.1 General.

- (a) As of the effective date of termination of this Agreement with respect to a Product(s) or all Products in the case of termination of this Agreement in its entirety (each such Product, the "Verve Terminated Product"), (a) all rights and licenses granted to Verve by Beam or its Affiliates under Article 2 will terminate with respect to the Verve Terminated Product, (b) no later than [**] after the effective date of such termination, each Party shall return or cause to be returned to the other Party all Confidential Information in tangible form received from the other Party and all copies thereof; provided, however, that each Party may retain one copy of Confidential Information received from the other Party in its confidential files for record purposes and, unless this Agreement has been terminated by Verve under Section 14.3, Beam shall be permitted to maintain Confidential Information of Verve necessary or useful to exploit the Verve Terminated Product(s) in accordance with its ongoing rights and subject to the confidentiality and non-use obligations under this Agreement, and (c) except for the surviving provisions set forth in Section 14.7, the rights and obligations of the Parties hereunder shall terminate as of the effective date of termination. In the case of termination of this Agreement with respect to [**] as a Licensed Target by Beam pursuant to Section 14.4.1, all Products directed towards such Licensed Target shall be deemed to be Verve Terminated Products.
- (b) As of the effective date of termination of this Agreement with respect to a GalNAc Product, Lipid Technology Product, or [**] Product (each such Product, the "Beam Terminated Product"), (a) all rights and licenses granted to Beam by Verve or its Affiliates under Article 2 (except Section 2.1.8 and Section 2.1.11(b)) will terminate with respect to the Beam Terminated Product, (b) no later than [**] after the effective date of such termination, each Party shall return or cause to be returned to the other Party all Confidential Information in tangible form received from the other Party and all copies thereof; provided, however, that each Party may retain one copy of Confidential Information received from the other Party in its confidential files for record purposes, and (c) except for the surviving provisions set forth in Section 14.7, the rights and obligations of the Parties hereunder shall terminate as of the effective date of termination.

14.6.2 Other Effects of Termination. Except for termination of this Agreement by Verve under Section 14.3,

(a) Where permitted by Applicable Law, upon written request, Verve shall (i) assign to Beam all of its right, title and interest in and to, and transfer possession to Beam of, all Regulatory Documentation (including, for

clarity, regulatory approvals) then in its name specific to any Verve Terminated Product other than (A) an Independent Product that is not a Collaboration Product or (B) a former Collaboration Product for which Beam exercised the Beam Opt-Out Option if Verve has terminated this Agreement within [**] following Beam's exercise of such Beam Opt-Out Option (such Verve Terminated Product, other than as described in the foregoing clauses (A) and (B), a "Terminated Reversion Product"), in the same form in which Verve maintains such Regulatory Documentation, or (ii) in the case of any Regulatory Documentation that is applicable, but not specific, to a Terminated Reversion Product, grant a "right of reference," as that term is defined in 21 C.F.R. § 314.3(b), or a comparable right existing under the Applicable Laws of any other jurisdiction, to such Regulatory Documentation solely for use in the Development, Manufacture, Commercialization or exploitation of such Terminated Reversion Product, and, in each case (clauses (i) and (ii)), upon request execute and deliver such additional documents or instruments reasonably necessary to effect such transfer or right of reference, in each case at Beam's cost and expense;

- (b) Upon written request, Verve shall grant and hereby grants, and shall cause its Affiliates to grant, to Beam an exclusive (even as to Verve and its Affiliates), perpetual, irrevocable, royalty-bearing (as set forth in and subject to this Section 14.6.2(b)) license under the Patent Rights and Know-How Controlled by Verve or its Affiliates as of the effective date of termination that either (i) claim or cover the composition, use or manufacture of the applicable Terminated Reversion Product(s) or (ii) were otherwise used or practiced in the Development, Manufacture, Commercialization or exploitation of the Terminated Reversion Product(s) on or prior to the effective date of termination (collectively. "Post-Termination Licensed Technology"), solely to Develop, Manufacture, Commercialize or otherwise exploit such Terminated Reversion Product(s) in the Field in the Territory, provided, however, that in the case of any such Patent Right or Know-How that requires payment to a Third Party pursuant to an applicable license or other agreement, such Patent Right or Know-How shall be [**] to such Third Party as a result of Beam's exercise of such license. Unless Beam terminates this Agreement for Verve's material breach of this Agreement under Section 14.4.1 (in which case no royalties are owed), Beam will pay Verve royalties equal to [**] percent ([**]%) of the annual aggregate Net Sales resulting from the sale of each such Terminated Reversion Product in the Field in the Territory and such royalties will be due to Verve, on a Product-by-Product and country-bycountry basis for the duration of the Royalty Term for the applicable Terminated Reversion Product in the applicable country as if this Agreement had stayed in effect. [**].
- (c) Unless expressly prohibited by any Regulatory Authority, upon written request of Beam, Verve shall transfer control to Beam conduct of any

Clinical Trials of such Terminated Reversion Product(s) being conducted as of the effective date of termination and continue to conduct such Clinical Trial(s) in accordance with a budget and plan agreed upon by the Parties, at Beam's cost and expense, for up to [**] to enable such transfer to be completed without interruption of such Clinical Trial(s); <u>provided</u> that Beam shall not have any obligation to continue any Clinical Trial unless required by Applicable Law;

- (d) To the extent that, as of the effective date of termination of this Agreement, Verve has existing and ongoing contracts with Third Parties related to the Development, Manufacture or Commercialization of the Terminated Reversion Product(s), at the written request of Beam, Verve will use good faith commercially reasonable efforts to transfer such contracts and arrangements to Beam if specific to the Terminated Reversion Product(s), or, if such contracts and arrangements relate to more than solely the Terminated Reversion Product(s), use good faith commercially reasonable efforts to assign contracts and arrangements to Beam in part or facilitate separate arrangements with Beam;
- (e) At Beam's written request, Verve shall deliver such quantities of the applicable Terminated Reversion Product(s) that Verve or its Affiliates has in its respective inventory or control (including inventory in its control on the premises of a Third Party subcontractor) as of the date of Beam's request; provided that Beam shall reimburse Verve for the Cost of Goods Manufactured and the costs of shipping and handling with respect to such quantities; provided further that, with respect to a Collaboration Product, Beam shall only be obligated to reimburse Verve for any portion of the costs thereof not previously reimbursed pursuant to this Agreement.
- (f) If Beam does not manufacture the applicable Terminated Reversion Product(s) either itself or on its behalf, Verve shall supply to Beam such reasonable quantities of such Terminated Reversion Product(s) as Beam indicates in written forecasts and orders from time to time, until the earlier of (i) such time as Beam has established an alternative, validated source of supply for such Terminated Reversion Product(s) and (ii) the [**] of the effective date of termination of this Agreement. The costs to Beam for supply of such Terminated Reversion Product(s) from Verve shall be equal to Verve's Cost of Goods Manufactured for such Terminated Reversion Product(s) [**]. Notwithstanding anything to the contrary in this Agreement, if any such Terminated Reversion Product is manufactured for Verve by a Third Party contract manufacturer pursuant to a written contract, then Verve may satisfy its obligations pursuant to this Section 14.6.2(f) with respect to such Terminated Reversion Product by assigning its rights and obligations under such contract (or the portion of such contract pertaining to such Terminated Reversion Product) to Beam.

- (g) Verve shall, at the written request and expense of Beam, provide Beam with such assistance as is reasonably necessary to effectuate a smooth and orderly transition to Beam or its designee of any Development, Manufacture and Commercialization activities relating to the applicable Terminated Reversion Product(s) so as to minimize the disruption of such activities, provided, however, that Verve shall not be obligated to initiate any new substantive activity, distinct from any previously ongoing substantive activity, that would itself create any new obligations on the part of Verve that would continue following such termination. Further, upon Beam's written request, Verve shall make its personnel reasonably available to provide such technical assistance, at no cost to Beam (except for reimbursement of Verve's direct out of pocket costs therefor), as may reasonably be requested to transfer all Manufacturing technology Controlled by Verve or its Affiliates that is or had been used by or on behalf of Verve and its Affiliates in connection with the Manufacture of any Terminated Reversion Product.
- 14.6.3 **Termination for Bankruptcy**. If this Agreement is terminated by either Party pursuant to Section 14.4.2, all licenses and rights to licenses granted under or pursuant to this Agreement by the non-terminating Party to the terminating Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the "Code"), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code. The Parties agree that the terminating Party, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against the non-terminating Party under the Code, the terminating party shall be entitled to a complete duplicate of or complete access to, any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to the terminating Party (i) upon any such commencement of a bankruptcy proceeding upon written request therefor by the terminating Party, unless the non-terminating Party elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of the non-terminating Party upon written request therefor by the terminating Party. The foregoing provisions of Section 14.6.3 are without prejudice to any rights that either Party may have arising under the Code or other Applicable Law.
- 14.6.4 <u>Assignment to Beam of [**] Patent Rights</u>. In the case of termination of this Agreement in its entirety by either Party, termination of this Agreement with respect to [**] as a Licensed Target by Beam pursuant to Section 14.4.1 or termination of this Agreement by Verve pursuant to Section 14.2 with respect to all Licensed Products directed to [**] as a Licensed Target, Verve shall, within [**] following the date of such termination, assign, transfer, convey and deliver to Beam, all of Verve's right, title and interest in, to and under the [**] Patent Rights, and promptly execute an assignment of the [**] Patent Rights in forms registrable or recordable in the United States Patent and Trademark Office or

applicable foreign offices to the extent necessary to assign the [**] Patent Rights, all in forms reasonably acceptable to Beam. Upon such termination and until completion of the assignment referred to in this <u>Section 14.6.4</u>, Verve hereby grants, and shall cause its Affiliates to grant, to Beam a fully paid up, royalty free, irrevocable, perpetual exclusive (even as to Verve and its Affiliates) license under the [**] Patent Rights, with a right to grant and authorize the further grant through multiple tiers of sublicenses for any and all purposes.

14.7 Effect of Termination; Survival. Termination of this Agreement shall not relieve the Parties of any obligation accruing upon or prior to such termination. Any termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement upon or prior to termination, including without limitation (a) obligations to pay any license fees or milestones that accrue under this Agreement upon or prior to termination and (b) the obligation to share Shared Costs incurred prior to such termination in accordance with this Agreement, and to share the Collaboration Territory Revenue from Products sold prior to such termination, in the case of both clause (a) and (b) above, in accordance with the provisions of Article 9. The provisions of Article 10 shall survive the termination of this Agreement and shall continue in effect for [**] following such termination. In addition, the provisions of Section 2.1.8 (Verve Base Editing Technology), Section 2.1.11 (Freedom to Operate Licenses from Verve), Section 2.2.4, Section 2.2.5, Section 2.2.6(c), Section 2.2.6(d), Section 2.4.2, Section 2.7.3 (Unauthorized Use of Party Materials), Section 2.7.4 (Title to Party Materials; Return), Article 5 (Beam Opt-in Option) (solely with respect to any Base Editor Product [**], and excluding termination of this Agreement by Verve pursuant to Section 14.4), Section 9.7 (Currency Exchange) (solely with respect to Terminated Reversion Products), Section 9.8 (Record-Keeping and Audit), Section 9.9 (Income Tax Withholding) (solely with respect to Terminated Reversion Products and payment obligations accrued under this Agreement upon or prior to termination), Section 9.10 (Late Payments) (solely with respect to Terminated Reversion Products and payment obligations accrued under this Agreement upon or prior to termination), Section 12.1 (Ownership of Intellectual Property), Section 12.2.5 (Filing, Prosecution and Maintenance of Joint Collaboration Patent Rights), Sections 12.3 (Verve Product Competitive Infringement) through 12.8 (Enforcement and Defense of Other Patent Rights and Know-How) (solely with respect to Joint Collaboration Patent Rights), Article 13 (Indemnification), Section 14.6 (Effects of Termination), this Section 14.7 (Effect of Termination; Survival), and Article 15 (Miscellaneous) shall each survive termination of this Agreement in its entirety and all definitions relating to the foregoing, shall survive any termination of this Agreement.

Article 15 MISCELLANEOUS

15.1 Use of Affiliates. Either Party shall have the right to exercise its rights and perform its obligations under this Agreement either itself or through any of its Affiliates. In addition, in each case where a Party's Affiliate has an obligation pursuant to this Agreement or performs an obligation pursuant to this Agreement, (a) such Party shall cause and compel such Affiliate to perform such obligation and comply with the terms of this Agreement and (b) any breach of the terms or conditions of this Agreement by such Affiliate shall be deemed a breach by such Party of such terms or conditions, for which such Party is liable.

- 15.2 Interpretation. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof. (g) all references herein to Sections or Schedules shall be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or."
- 15.3 Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party or any of its Affiliates, potentially including, but not limited to, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, epidemics, pandemics, outbreaks of infectious diseases (provided that the Parties acknowledge that COVID-19 in its state as of the Restatement Effective Date shall not constitute a force majeure circumstance for the purpose of this Agreement) or other acts of God, or acts, omissions or delays in acting by any Governmental Authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to resume performance.
- **15.4 Assignment**. Except as provided in this Section 15.4 and Section 2.2.3, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party; provided, however, that (a) Verve or Beam may, without such consent, assign this Agreement and its rights and obligations hereunder to an Affiliate, in whole or in part and (b) any Party may assign this Agreement and its rights and obligations hereunder, in whole or in part, in connection with the transfer or sale of all or substantially all of its assets related to the

subject matter of this Agreement, or in the event of its merger or consolidation or change in control or similar transaction. Any attempted assignment not in accordance with this <u>Section 15.4</u> shall be void and unenforceable. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement.

- 15.5 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.
- **15.6 Notices**. All notices which are required or permitted pursuant to this Agreement shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Beam: Beam Therapeutics Inc.

26 Landsdowne Street Cambridge, MA 02139

Email: [**]
Attn: CEO

With a copy to: Cooley LLP

One Freedom Square Reston Town Center 11951 Freedom Drive Reston, VA 20190-5656

Telephone: [**]
Facsimile: [**]
E-mail: [**]

Attn: Kenneth J. Krisko

If to Verve: Verve Therapeutics, Inc.

500 Technology Square, Suite 901

Cambridge, MA 02139

E-mail: [**]
Attn: President

With a copy to: Wilson Sonsini Goodrich & Rosati

650 Page Mill Road Palo Alto, CA 94304 Telephone: [**] Facsimile: [**] E-mail: [**]

Attn: Lowell A. Segal

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a Business Day (or if delivered or sent on a non-Business Day, then on the next Business Day); (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) Business Day following the date of mailing, if sent by mail.

15.7 Dispute Resolution. If any dispute between the Parties arises out of or relates to this Agreement, other than a dispute within the JSC to be resolved as set forth in Section 3.3.3, (a "**Dispute**"), either Party by written notice to the other Party may have such issue referred for resolution to the Senior Officers. The Senior Officers shall meet promptly to discuss the matter submitted and to determine a resolution. If the Senior Officers are unable to resolve the Dispute within [**] after it is referred to them, then the Parties may pursue all other rights and remedies available to them under this Agreement, including the right to

terminate this Agreement, and the matter shall, upon written notice of either Party to the other Party, be resolved by final, binding arbitration in accordance with <u>Section 15.8</u>.

15.8 Governing Law and Arbitration. This Agreement will be governed by, and construed in accordance with, the substantive laws of the Commonwealth of Massachusetts and the patent laws of the United States, in each case without giving effect to any choice or conflict of law provision. Any arbitration of a Dispute shall be administered by the American Arbitration Association ("AAA") under its Commercial Arbitration Rules then in effect, except as modified in this Agreement. The arbitration shall be conducted in the English language, by a single arbitrator. If the Parties are unable to agree on an arbitrator, the arbitrator shall be selected in accordance with the AAA Commercial Arbitration Rules. Each Party shall have the right to engage an independent expert with experience in the subject matter of the Dispute to advise the arbitrator, but final decision making authority shall remain in the arbitrator. The arbitrator shall determine what discovery will be permitted, including depositions, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery, provided that the arbitrator shall permit such discovery as he or she deems necessary to permit an equitable resolution of the Dispute while allowing senior management of a Party sufficient access to discovery and expert reports such as to allow the Party's senior management to assess the merits of the other Party's positions to facilitate amicable resolution prior to a hearing on the merits and a final decision by the arbitrator. except for any discovery and expert reports that the producing Party believes in good faith are highly sensitive such that disclosure of the same to senior management of the other Party is substantially likely to cause injury to the producing Party. The Parties and the arbitrator shall use reasonable efforts to complete any such arbitration within [**]. The Parties agree that the decision of the arbitrator shall be the binding remedy between them regarding the Dispute presented to the arbitrator, and judgment upon the award rendered by the arbitrator may be entered in any court of competent jurisdiction. Unless otherwise agreed by the Parties, the arbitration proceedings shall be conducted in Boston, Massachusetts. The Parties shall share equally the cost of the arbitration filing and hearing fees, the cost of an independent expert retained by the arbitrator and the cost of the arbitrator and administrative fees of AAA. Each Party shall bear its own costs and attorneys' and witnesses' fees and associated costs and expenses. Each Party agrees not to commence any legal proceedings based upon or arising out of this Agreement in a court of law, except that a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss or damage on a provisional basis, pending the selection of the arbitrator or pending the arbitrator's determination of the merits of any Dispute pursuant to this Section 15.8. All arbitration proceedings hereunder shall be confidential. Except as required by Applicable Law or the rules of a recognized stock exchange or automated quotation system applicable to the applicable Party, neither Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings or decision of the arbitrator without prior written consent of the other Party.

15.9 Entire Agreement; Amendments. This Agreement, together with the Schedules hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof are superseded

by the terms of this Agreement, including (a) the Existing Confidentiality Agreement; <u>provided that</u> nothing in this <u>Section 15.9</u> shall affect a Party's ability to enforce the terms of the Existing Confidentiality Agreement with respect to the subject matter hereof for actions or omissions taking place prior to the Original Agreement Effective Date, and (b) the Material Transfer Agreement. The Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of each of the Parties.

- **15.10 Headings**. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.
- **15.11 Independent Contractors**. It is expressly agreed that Beam and Verve shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency, provided, in the event Beam exercises any Beam Opt-In Option, the Parties shall confer and determine by mutual written agreement whether the Parties have entered into a partnership solely for U.S. income tax purposes. Neither Beam nor Verve shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.
- **Waiver**. The waiver by either Party of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.
- **15.13** Cumulative Remedies. Except as expressly set forth in this Agreement, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law.
- **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.
- **Business Day Requirements**. In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.
- **Counterparts**. This Agreement may be signed in any number of counterparts (facsimile and electronic transmission included), each of which shall be deemed an original, but all of which shall constitute one and the same instrument. After facsimile or electronic transmission, the Parties agree to execute and exchange documents with original signatures upon written request by either Party. Counterpart signatures delivered via facsimile or

e-mail in PDF or similar electronic format shall have the same binding effect as original signatures.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Restatement Effective Date.

VERVE THERAPEUTICS, INC.	BEAM THERAPEUTICS INC.
BY:_ <u>/s/ Andrew Ashe</u>	BY: <u>/s/ John Evans</u>
NAME: Andrew Ashe	NAME: John Evans
TITLE: President and Chief Operating Officer	TITLE: Chief Executive Officer

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

STRATEGIC COLLABORATION AND LICENSE AGREEMENT

BETWEEN

VERTEX PHARMACEUTICALS INCORPORATED

AND

VERVE THERAPEUTICS, INC.

STRATEGIC COLLABORATION AND LICENSE AGREEMENT

This Strategic Collaboration and License Agreement (this "Agreement") is entered into as of July 18, 2022 (the "Effective Date") by and between Vertex Pharmaceuticals Incorporated, a corporation organized under the laws of the Commonwealth of Massachusetts ("Vertex") and Verve Therapeutics, Inc., a corporation organized under the laws of the State of Delaware ("Company"). Vertex and Company each may be referred to herein individually as a "Party" or collectively as the "Parties."

RECITALS

WHEREAS, Company owns or controls certain Patents and Know-How relating to Delivery Systems and Gene Editing Systems;

WHEREAS, Vertex is a biopharmaceutical company that possesses expertise in developing and commercializing human therapeutics;

WHEREAS, Vertex and Company desire to enter into this Agreement, pursuant to which (a) the Parties would collaborate under a Research Plan to discover and Research Licensed Agents and Products in the Field and (b) Vertex would have the right to Research, Develop, Manufacture and Commercialize Licensed Agents and Products in the Field; and

NOW, THEREFORE, in consideration of the respective covenants, representations, warranties and agreements set forth herein, the Parties hereto agree as follows:

ARTICLE 1. DEFINITIONS

For purposes of this Agreement, the following capitalized terms will have the following meanings:

- 1.1. "AAA" has the meaning set forth in Section 11.12.2.
- 1.2. "[**]" means [**].
- 1.3. "[**]" has the meaning set forth in Section [**].
- 1.4. "[**]" has the meaning set forth in Section [**].
- 1.5. "[**]" means any Company Agreement Technology, Company System Technology, or Joint Agreement Technology that relates solely to: (a) the composition, method of manufacture or method of use of one or more Licensed Agents or Products; (b) [**]; or (c) without limitation to clause (a), methods of use or treatment of a Gene Editing System (or a product containing a Gene Editing System) directed to [**].
- 1.6. "Acquisition Transaction" has the meaning set forth in Section 4.7.

- 1.7. "Acquirer" means: (a) any Third Party that becomes an Affiliate of a Party through a Change of Control of such Party; and (b) the Affiliates of any Third Party described in subsection (a) immediately prior to the closing of such Change of Control.
- 1.8. "Acting Party" has the meaning set forth in Section 5.11.3.
- 1.9. "Additional Amount" has the meaning set forth in Section 5.11.3.
- 1.10. "Additional Research Activities" has the meaning set forth in Section 2.1.6(a).
- 1.11. "Additional Research Budget" has the meaning set forth in Section 2.1.6(a).
- 1.12. "Additional Research Plan" has the meaning set forth in Section 2.1.6(a).
- 1.13. "Adverse Event" has the meaning set forth in the Applicable Law for such term (or comparable term), and will generally mean any untoward medical occurrence in a subject in any Clinical Trial or patient who has received a Licensed Agent, Product, medical device or placebo, and which does not necessarily have a causal relationship with such Licensed Agent, Product, medical device or placebo, including any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of the applicable Licensed Agent, Product, medical device or placebo whether or not related to such Licensed Agent, Product, medical device or placebo.
- 1.14. "Affiliate" means, with respect to a Person, as of any point in time and for so long as such relationship continues to exist with respect to such Person, any other Person that controls, is controlled by or is under common control with such Person. A Person will be regarded as in control of another Person if it (a) owns or controls, directly or indirectly, more than 50% of the equity securities of the subject Person entitled to vote in the election of directors (or, in the case of a Person that is not a corporation, for the election of the corresponding managing authority), or (b) possesses, directly or indirectly, the power to direct or cause the direction of the management or policies of such Person (whether through ownership of securities or other ownership interests, by contract or otherwise).
- 1.15. "**Agreement**" has the meaning set forth in the Preamble.
- 1.16. "**Agreement Activities**" means the performance of Research, Development, Manufacture or Commercialization activities under this Agreement.
- 1.17. "Alliance Manager" has the meaning set forth in Section 3.5.1.
- 1.18. "Annual Net Sales" means, with respect to a Product, the aggregate Net Sales of such Product sold by Vertex, its Affiliates or Sublicensees in the Field in the Territory during a Calendar Year and only during the Royalty Term for such Product in the applicable country.

- 1.19. "Applicable Law" means all applicable laws, statutes, rules, regulations and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, agency or other body, domestic or foreign, including any applicable rules, regulations, guidelines, or other requirements of the Regulatory Authorities that may be in effect from time to time.
- 1.20. "Approval Application" means a BLA, NDA or similar application or submission for a Product intended for use in connection with a Product filed with a Regulatory Authority in a country or group of countries to obtain marketing approval for a biological or pharmaceutical product, in that country or group of countries.
- 1.21. "Audited Party" has the meaning set forth in Section 5.12.2.
- 1.22. "Auditing Party" has the meaning set forth in Section 5.12.2.
- 1.23. "Baseball Arbitration" means the arbitration process set forth in Schedule 1.23.
- 1.24. "[**]" has the meaning set forth in Section [**].
- 1.25. "[**]" has the meaning set forth in Section [**].
- 1.26. "BLA" means a Biologics License Application that is submitted to the FDA for marketing approval for a Product pursuant to 21 C.F.R. § 601.2, or any substantially equivalent application in a jurisdiction outside the United States.
- 1.27. "Breaching Party" has the meaning set forth in Section 9.2.2.
- 1.28. "Build-Out Expenses" has the meaning set forth in Section 1.124(b).
- 1.29. "Business Day" means, with respect to performance of an obligation or exercise of a right under this Agreement, any day other than a Saturday or Sunday or any city, state or federal holiday observed by the Party responsible for such performance or having such right.
- 1.30. "Calendar Quarter" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 or December 31, during the Term, or the applicable part thereof during the first or last calendar quarter of the Term.
- 1.31. "Calendar Year" means any calendar year ending on December 31, or the applicable part thereof during the first or last year of the Term.
- 1.32. "CDA" has the meaning set forth in Section 1.57.
- 1.33. "Change of Control" means, with respect to a Party: (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than 50%

of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation; (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of more than 50% of the combined voting power of the outstanding securities of such Party; or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's business or assets to which the subject matter of this Agreement relates.

- 1.34. "Clinical Trial" means a study in humans that is required to be conducted in accordance with GCP and is designed to generate data in support of an Approval Application.
- 1.35. "Combination Product" has the meaning set forth in Section 1.133.
- 1.36. "Commercialization Expenses" means, with respect to a Profit Share Product, [**].
- 1.37. "Commercialize" or "Commercializing" means to: (a) market, promote, distribute, offer for sale, sell, have sold, import, export or otherwise commercialize a Product; or (b) conduct activities, other than Research, Development and Manufacturing, in preparation for the foregoing activities, including obtaining Price Approval. When used as a noun, "Commercialization" means any activities involved in Commercializing.
- 1.38. "Commercialization Plan" means, with respect to a Profit Share Product, the good faith, non-binding plan setting forth at a high level the anticipated Commercialization activities for such Profit Share Product in the Field in the Territory.
- 1.39. "Commercially Reasonable Efforts" means with respect to the efforts to be expended by any Person with respect to any objective, reasonable, diligent and good faith efforts to accomplish such objective. With respect to Vertex's obligations set forth in Section 2.6, "Commercially Reasonable Efforts" means [**]. "Commercially Reasonable Efforts" will be determined on a country-by-country basis in the relevant countries, and activities that are conducted in one country that have an effect on achieving the relevant objective in another country will be considered in determining whether Commercially Reasonable Efforts have been applied in such other countries.
- 1.40. "Common Ownership Legislation" means the legislation on conditions for patentability and novelty, as codified at 35 U.S.C. § 102(c) (Common Ownership Under Joint Research Agreements).
- 1.41. "Company" has the meaning set forth in the Preamble.
- 1.42. "Company's Knowledge" means the actual knowledge of the individuals identified on <u>Schedule 1.42</u> after due inquiry of their direct reports and other

- employees of Company expected to have pertinent information with respect to the applicable matter (other than outside legal counsel).
- 1.43. "Company Activity Expenses" means, with respect to a Profit Share Product, all Expenses incurred by Company or its Affiliates on or after the Profit Share Effective Date for: (a) Research Activities performed in accordance with the Research Plan (including the Research Budget) (or Additional Research Plan and Additional Research Budget); and (b) Other Company Activities performed in accordance with the applicable Other Company Activities Plan, including the budget set forth therein; in each case ((a) and (b)), to the extent reasonably allocable to such Profit Share Product (including the Licensed Agent in such Profit Share Product).
- 1.44. "Company Agreement Know-How" means Know-How, other than Vertex System Know-How, that is Created solely by Company or its Affiliates or Third Parties acting on its or their behalf, in each case, in the performance of Agreement Activities.
- 1.45. "Company Agreement Patents" means Patents that claim any Company Agreement Know-How and do not claim Vertex Agreement Know-How, Joint Agreement Know-How or Vertex System Know-How.
- 1.46. "Company Agreement Technology" means the Company Agreement Know-How and Company Agreement Patents.
- 1.47. "Company Delivery System" means any Delivery System that: (a) is, in whole or in part, Covered by any Patent Controlled by Company or any of its Affiliates; or (b) incorporates or embodies any Know-How Controlled by Company or any of its Affiliates, including Company's GalNAc LNP.
- 1.48. "Company Gene Editing System" means any Gene Editing System that: (a) is, in whole or in part, Covered by any Patent Controlled by Company or any of its Affiliates; or (b) incorporates or embodies any Know-How Controlled by Company or any of its Affiliates.
- 1.49. "Company Indemnified Party" has the meaning set forth in Section 8.1.1.
- 1.50. "Company In-License Agreements" means [**].
- 1.51. "Company System Know-How" means any Know-How, other than any Know-How that constitutes an Overlapping Improvement, that is Created in the performance of Agreement Activities either (a) solely by Company or its Affiliates or Third Parties acting on its or their behalf, (b) jointly by both Parties or their respective Affiliates or Third Parties acting on their behalf or (c) solely by Vertex or its Affiliates or Third Parties acting on its behalf, in each case ((a)-(c)), solely to the extent that such Know-How: [**].

- 1.52. "Company System Patents" means Patents that claim any Company System Know-How and do not claim Vertex Agreement Know-How, Joint Agreement Know-How, Vertex System Know-How or Overlapping Improvements.
- 1.53. "Company System Technology" means the Company System Know-How and Company System Patents.
- 1.54. "Competitive Infringement" means an infringement, unauthorized use, misappropriation or threatened infringement of: (a) the Licensed Technology by a Third Party by reason of the making, using, offering to sell, selling, importing or other exploitation of a Gene Editing System or Delivery System (or an agent or product containing a Gene Editing System or Delivery System) that would be competitive with a Licensed Agent or Product; or (b) the [**] or Joint Agreement Technology by reason of the making, using, offering to sell, selling, importing or other exploitation of any product that would be competitive with a Licensed Agent or Product; in each case ((a) and (b)), in the Field in the Territory.
- 1.55. "Competitor" means any Third Party that is [**].
- 1.56. "Compliance" means, with respect to a Party, the adherence by such Party and its Affiliates to Applicable Law and such Party's Party Specific Regulations, in each case with respect to the activities to be conducted under this Agreement.
- 1.57. "Confidential Information" means, with respect to each Party, all Know-How or other information (including proprietary information (whether or not patentable) regarding or embodying such Party's technology, agents, products, business information or objectives) that is communicated in any way or form by or on behalf of the Disclosing Party to the Receiving Party or its permitted recipients pursuant to this Agreement or that certain Mutual Confidentiality Agreement between Vertex and Company dated [**] (the "CDA"), whether or not such Know-How or other information is identified as confidential at the time of disclosure.
 - 1.57.1. Except to the extent disclosed in a mutually agreed press release or other mutually agreed public communication, the terms of this Agreement will be considered Confidential Information of both Parties, with both Parties deemed to be the Receiving Party of such Confidential Information.
 - 1.57.2. All (a) information and data specifically applicable to Licensed Agents or Products generated on or after the Effective Date pursuant to activities contemplated by this Agreement and (b) Vertex System Know-How will, in each case ((a) and (b)), be considered Vertex's Confidential Information, with Company deemed to be the Receiving Party of such Confidential Information and the exceptions set forth in clauses (A), (D) and (E) of Section 1.57.6 below will not apply to such Confidential Information; *provided*, *however*, that the foregoing will not prevent Company from (y) subject to the terms and conditions of this Agreement, including the grant of any exclusive rights or covenants to Vertex

hereunder, using or disclosing any Company Agreement Know-How or Company System Know-How for Company's internal purposes, including research, development, manufacture, commercialization and other exploitation of its technology and products, or (z) using or disclosing any Company Agreement Know-How or Company System Know-How after expiration or termination of this Agreement.

- 1.57.3. Subject to Section 1.57.2, all Company System Know-How will be considered Company's Confidential Information, with Vertex deemed to be the Receiving Party of such Confidential Information and the exceptions set forth in clauses (A), (D) and (E) of Section 1.57.6 below will not apply to such Confidential Information.
- 1.57.4. Subject to Section 1.57.2, all Joint Agreement Know-How will be considered Vertex's Confidential Information and Company's Confidential Information, with each Party deemed to be a Receiving Party of such Confidential Information and the exceptions set forth in clauses (A), (D) and (E) of Section 1.57.6 below will not apply to such Confidential Information; *provided*, *however*, that the foregoing will not prevent either Party from, subject to the terms and conditions of this Agreement, including the grant of any exclusive rights or covenants to Vertex hereunder, using or disclosing any Joint Agreement Know-How for its internal purposes, including research, development, manufacture, commercialization and other exploitation of its technology and products.
- 1.57.5. For clarity, subject to Section 1.57.2, all Know-How solely owned by one Party will be considered such Party's Confidential Information, with the non-owning Party deemed to be the Receiving Party of such Confidential Information.
- 1.57.6. Notwithstanding any provision of this Section 1.57 to the contrary, Confidential Information does not include any Know-How or information that: (A) was already known by the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure by or on behalf of the Disclosing Party; (B) was generally available to the public or part of the public domain at the time of its disclosure to the Receiving Party; (C) became generally available to the public or part of the public domain after its disclosure to the Receiving Party, other than through any act or omission of the Receiving Party in breach of its obligations under this Agreement; (D) is disclosed to the Receiving Party (other than under an obligation of confidentiality) by a Third Party who has no obligation to the Disclosing Party not to disclose such information to the Receiving Party; or (E) is independently Created by or on behalf of the Receiving Party without the use of any Confidential Information belonging to the Disclosing Party. Confidential Information disclosed to the Receiving Party hereunder will not be deemed to fall within the foregoing exceptions merely because broader or related information falls within such

exceptions, nor will combinations of elements or principles be considered to fall within the foregoing exceptions merely because individual elements of such combinations fall within such exceptions.

- 1.58. "Control" or "Controlled" means, with respect to a Party or any of its Affiliates and to any Know-How, Patent, or Regulatory Filing, possession on the Effective Date or at any time during the Term of the ability by such Party or such Affiliate (whether by sole or joint ownership, license or otherwise), other than pursuant to this Agreement, to grant a license, access or other right in, to or under such Know-How, Patent or Regulatory Filing in the manner contemplated by this Agreement without violating the terms of any agreement with a Third Party. Notwithstanding the foregoing: (a) any Know-How, Patent or Regulatory Filing in-licensed or acquired by Company or its Affiliates under a New Company Agreement shall not be deemed "Controlled" by Company or its Affiliates unless and until Vertex provides a New Company Agreement Election Notice with respect to such New Company Agreement (and only for so long Vertex has not has not exercised its right to abandon its payment obligations pursuant to Section 5.7.3(c)); and (b) notwithstanding anything to the contrary in this Agreement, a Party or its Affiliates will be deemed to not Control any Patents, Know-How or Regulatory Filings that are owned or controlled by an Acquirer (regardless of whether the Acquirer is an Affiliate after a Change of Control) (i) prior to the closing of the Change of Control pursuant to which such Acquirer became an Affiliate of such Party, except to the extent that any such Patents, Know-How or Regulatory Filings are used or practiced by or on behalf of such Party or any of its Affiliates in the performance of Agreement Activities, or (ii) after the closing of such Change of Control to the extent that such Patents, Know-How or Regulatory Filings (A) are Created by such Acquirer after the closing of such Change of Control without using or incorporating (1) such Party's or its pre-existing Affiliates' Know-How or Patents or (2) any Confidential Information of Vertex. and (B) are not used or practiced by or on behalf of such Party or any of its Affiliates in the performance of Agreement Activities.
- 1.59. "Cost of Goods Sold" means the cost of goods sold or cost of services sold, as applicable, [**].
- 1.60. "Cover," "Covering" or "Covers" means, as to an agent, product or other technology and Patent, that, in the absence of a license granted under, or ownership of, such Patent, the making, having made, using, selling, offering for sale or importation of such agent, product or other technology would infringe such Patent (or, as to a pending claim included in such Patent, the making, using, keeping, selling, offering for sale or importation of such agent, product or other technology would infringe such Patent if such pending claim were to issue in an issued patent without modification) in the country in which such activity occurs.
- 1.61. "Created" means (a) with respect to any Know-How constituting an invention, invented and (b) with respect to any other Know-How, discovered, developed or created.

- 1.62. "Delivery System" means a vehicle [**].
- 1.63. "Development" means, with respect to a Product or Licensed Agent contained in a Product, all clinical and non-clinical research and development activities conducted after filing of an IND for such Product, including toxicology, pharmacology test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, Clinical Trials, regulatory affairs, pharmacovigilance, Clinical Trial regulatory activities and obtaining and maintaining Marketing Approval. When used as a verb, "Develop" or "Developing" means to engage in Development. "Development" shall be deemed to include the conduct of post-Marketing Approval studies for a Product (including Clinical Trials).
- 1.64. "Development Candidate Criteria" means the criteria set forth on Schedule 1.64.
- 1.65. "**Development Expenses**" means, with respect to a Profit Share Product or Licensed Agent contained in a Profit Share Product, [**].
- 1.66. "**Development Plan**" means, with respect to a Profit Share Product, the good faith, non-binding development plan setting forth at a high level the anticipated Development activities for such Profit Share Product in the Field in the Territory.
- 1.67. "Disclosing Party" has the meaning set forth in Section 10.1.
- 1.68. "**Dispute**" has the meaning set forth in Section 11.12.
- 1.69. "**Distracting Product**" has the meaning set forth in Section 4.7.
- 1.70. "Distributor" means a Third Party to whom Vertex or its Affiliates or Sublicensees grant a right to sell or distribute a Product, that purchases its requirements for such Product from Vertex or its Affiliates or Sublicensees and does not otherwise make any royalty or other payments to Vertex or its Affiliates or Sublicensees with respect to Vertex's, its Affiliates' or its Sublicensees' intellectual property rights or Products, including any payments that are calculated on the basis of a percentage of, or profit share on, such Third Party's sale of Products.
- 1.71. "Divest" means, with respect to a Distracting Product, the sale, exclusive license or other transfer by Company and its Affiliates of all of their research, development, manufacturing and commercialization rights with respect to such Distracting Product to a Third Party without the retention or reservation of any research, development, manufacturing or commercialization obligation, interest or participation rights (other than solely an economic interest or the right to enforce customary terms contained in the relevant agreements effectuating such transaction).
- 1.72. "**Effective Date**" has the meaning set forth in the Preamble.

- 1.73. "EMA" means the European Medicines Agency and any successor entity thereto.
- 1.74. "Equivalent Product" means, with respect to a particular Product in a particular country, a product on the market in such country commercialized by any Third Party that is not a Sublicensee and that did not purchase such product in a chain of distribution that included any of Vertex or its Affiliates or Sublicensees, that: (a) is approved by the applicable Regulatory Authority, under any then-existing laws and regulations in the applicable country pertaining to approval of generic or biosimilar biologic products, as a "generic" or "biosimilar" (or foreign equivalent) version of such Product, which approval relies on or references information in the Approval Application for such Product; or (b) is otherwise recognized by the applicable Regulatory Authority as a biosimilar or interchangeable product (or foreign equivalent) to such Product.
- 1.75. "Europe" means: (a) the economic, scientific and political organization of member states of the European Union as it may be constituted from time to time, which as of the Effective Date consists of Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and that certain portion of Cyprus included in such organization (the "European Union"); (b) the United Kingdom of Great Britain and Northern Ireland; (c) any member country of the European Economic Area that is not otherwise a member of the European Union; and (d) any country not otherwise included in clauses (a), (b) or (c) that participates in the unified filing system under the auspices of the EMA. Notwithstanding the foregoing, "Europe" will at all times be deemed to include each of Italy, Germany, France, the United Kingdom and Spain.
- 1.76. "**European Commission**" means the European Commission or any successor entity that is responsible for granting marketing approvals authorizing the sale of pharmaceuticals in the European Union.
- 1.77. **"European Union"** has the meaning set forth in Section 1.75.
- 1.78. "Executive Officers" means the Chief Executive Officer of Company and the Executive Vice President and Chief Scientific Officer of Vertex, or any executive vice president designated by a Party in writing who has the authority to resolve the applicable matter referred to the Executive Officers in accordance with this Agreement.
- 1.79. "Existing In-License Agreement" has the meaning set forth in Section 5.7.1.
- 1.80. "Existing In-License Agreement Net Sales" has the meaning set forth in Section 5.7.3(a)(i)(E).
- 1.81. "Expenses" means Out-of-Pocket Costs and FTE Costs.

- 1.82. "Exploit" means, with respect to a Licensed Agent or Product, to Research, Develop, Manufacture (including have Manufactured), use, keep, sell, offer for sale, import, export, Commercialize and otherwise exploit such Licensed Agent or Product.
- 1.83. "FDA" means the United States Food and Drug Administration and any successor entity thereto.
- 1.84. "FD&C Act" means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.
- 1.85. "Field" means the treatment, prevention and diagnosis of any human disease.
- 1.86. "Filing" has the meaning set forth in Section 6.2.1.
- 1.87. "First Commercial Sale" means with respect to a Product, [**].
- 1.88. **"Force Majeure"** means a condition, the occurrence and continuation of which is beyond the reasonable control of a Party, including an act of God, governmental acts or restrictions, war, civil commotion, labor strike or lock-out, epidemic or pandemic, flood, failure or default of public utilities or common carriers, and destruction of production facilities or materials by fire, earthquake, storm or like catastrophe.
- 1.89. "FTE" means [**] hours of work per annum devoted to or in support of (a) the Research Activities or Other Company Activities that is carried out by one or more qualified scientific or technical employees (for clarity, excluding Third Party contractors) of Company or its Affiliates or (b) Agreement Activities that is carried out by one or more qualified employees (for clarity, excluding Third Party contractors) of Vertex or its Affiliates.
- 1.90. "FTE Costs" means, for any period, the applicable FTE Rate multiplied by the number of FTEs who perform a specified activity under this Agreement.
- 1.91. "FTE Rate" means \$[**] per FTE; provided that such rates will increase or decrease on January 1 of each Calendar Year (starting with January 1, 2023) in accordance with the percentage year-over-year increase or decrease in the Consumer Price Index Urban Wage Earners and Clerical Workers, US City Average, All Items, 1982-84 = 100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index) over the 12 month period preceding each such January 1. The FTE Rate includes (a) all wages and salaries, employee benefits, bonus, travel and entertainment, supplies and other direct expenses and (b) indirect allocations, including all general and administrative expenses, human resources, finance, occupancy and depreciation.
- 1.92. "GAAP" means United States generally accepted accounting principles.

- 1.93. "GCP" means good clinical practices, which are the then-current standards for Clinical Trials for pharmaceuticals, as set forth in the FD&C Act, FDA's regulations and guidance, ICH Guideline E6 or other Applicable Law, and such standards of good clinical practice as are required by the Regulatory Authorities of Europe and other organizations and governmental authorities in countries for which the applicable Licensed Agent or Product is intended to be Developed, to the extent such standards are not less stringent than United States standards.
- 1.94. "Gene Editing System" means: (a) a gene editing or engineering system or technology [**]; and (b) nucleotide sequences (e.g., mRNA) encoding same.
- 1.95. "GLP" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, or comparable regulatory standards in jurisdictions outside of the United States, to the extent such standards are not less stringent than United States standards.
- 1.96. "GMP" means the then-current good manufacturing practices as specified in FDA's regulations, ICH Guideline Q7A, or equivalent laws, rules or regulations of an applicable Regulatory Authority at the time of manufacture, to the extent such standards are not less stringent than United States standards.
- 1.97. "Government Official" means (a) any elected or appointed government official (*e.g.*, a member of a ministry of health), (b) any employee or person acting for or on behalf of a government official, Governmental Authority, or other enterprise performing a governmental function, (c) any political party, candidate for public office, officer, employee, or person acting for or on behalf of a political party or candidate for public office, and (d) any employee or person acting for or on behalf of a public international organization (*e.g.*, the United Nations). For clarity, healthcare professionals or healthcare providers employed by government-owned hospitals will be considered Government Officials.
- 1.98. "Governmental Authority" means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.
- 1.99. "Grantor" has the meaning set forth in Section 5.7.2(a).
- 1.100. "IND" means any Investigational New Drug application filed with the FDA pursuant to 21 C.F.R. Part 312 or a clinical trial authorization or similar application or submission for Clinical Trial of a Product filed with a Regulatory Authority in a country or group of countries.
- 1.101. "IND Acceptance Date" means, (a) with respect to an IND in the United States, the later of (i) the occurrence of 30 days following the FDA's receipt of such IND if the FDA does not place a clinical hold with respect to such IND filing in such 30-day period and the IND filing has not been withdrawn in such 30-day period or (ii) if the FDA places a clinical hold with respect to such IND during such 30-day period, the FDA's notification of the lifting of such clinical hold and (b) with

- respect to an IND in a country other than the United States, the clearance of such IND in accordance with Applicable Law such that the Clinical Trial described in such IND may be initiated.
- 1.102. "IND-Enabling Toxicology Studies" means, with respect to a Product, animal toxicology studies conducted in accordance with applicable GLP that are suitable and intended to support an IND for such Product.
- 1.103. "**Indemnified Party**" has the meaning set forth in Section 8.1.4.
- 1.104. "**Indemnifying Party**" has the meaning set forth in Section 8.1.4.
- 1.105. "Indirect Tax" has the meaning set forth in Section 5.11.4.
- 1.106. "**Initiation**" or "**Initiate**" means, with respect to any Clinical Trial, first dosing of the first human subject in such Clinical Trial.
- 1.107. "**Insolvency Event**" has the meaning set forth in Section 9.2.4.
- 1.108. "**IP Committee**" has the meaning set forth in Section 3.3.
- 1.109. "Joint Agreement Know-How" means Know-How, other than Vertex System Know How and Company System Know-How, that is Created jointly by both Parties or their respective Affiliates or Third Parties acting on their behalf, in each case, in the performance of Agreement Activities (including in any meeting of the JRC). For clarity, for Know-How that is not an invention, neither of the following shall, on its own or in combination with each other, suffice to establish that such Know-How is Joint Agreement Know-How: (a) the mere existence of this Agreement; or (b) the mere disclosure or inclusion of an objective or problem to be solved in the Research Plan or in connection with Agreement Activities.
- 1.110. "Joint Agreement Patents" means Patents that (a) claim any Joint Agreement Know-How or (b) both (i) claim Company Agreement Know-How or Company System Know-How (on the one hand) and (ii) and separately claim Vertex Agreement Know-How or Vertex System Know-How (on the other hand).
- 1.111. "Joint Agreement Technology" means the Joint Agreement Know-How and Joint Agreement Patents.
- 1.112. "JRC" has the meaning set forth in Section 3.1.1.
- 1.113. "JSC" has the meaning set forth in Section 3.2.1.
- 1.114. "**Know-How**" means data, results, protocols, chemical structures, chemical sequences, materials, inventions, know-how, formulas, trade secrets, techniques, methods, processes, procedures and developments, and other scientific, technical or manufacturing information, whether or not patentable.

- 1.115. "Liability" has the meaning set forth in Section 8.1.1.
- 1.116. "Licensed Agent" means any agent containing a [**].
- 1.117. "Licensed Know-How" means any Know-How Controlled by Company or its Affiliates on the Effective Date, or that comes into Company's or its Affiliate's Control during the Term, that is necessary or reasonably useful to Research, Develop, Manufacture or Commercialize any Licensed Agent or Product in the Field.
- 1.118. "Licensed Patents" means any Patents Controlled by Company or its Affiliates on the Effective Date, or that come into the Company's or its Affiliate's Control during the Term, that (a) Cover any Licensed Agent or Product; or (b) are otherwise necessary or reasonably useful to Research, Develop, Manufacture or Commercialize any Licensed Agent or Product in the Field.
- 1.119. "Licensed Technology" means the Licensed Patents and Licensed Know-How.
- 1.120. "Licensee" has the meaning set forth in Section 5.7.2(b).
- 1.121. "[**]" has the meaning set forth in Schedule 1.121.
- 1.122. "Major European Market Country" means any one of the following countries: [**].
- 1.123. "Manufacture" or "Manufactured" or "Manufacturing" means activities directed to making, having made, producing, manufacturing, processing, filling, finishing, packaging, labeling, quality control testing and quality assurance release, shipping or storage of a Licensed Agent or Product.
- 1.124. "Manufacturing Expenses" means, with respect to a Profit Share Product:
 - (a) [**];
 - (b) [**]; and
 - (c) [**].
- 1.125. "Marketing Approval" means, with respect to a Product in a particular jurisdiction, all approvals (including any regular or accelerated approval of a BLA or NDA), licenses, registrations or authorizations necessary for the Commercialization of such Product in such jurisdiction, including, with respect to the United States, approval of an Approval Application for such Product by the FDA and with respect to Europe, approval of an Approval Application for such Product by the European Commission or the applicable Regulatory Authority in any particular country in Europe. For clarity, Marketing Approval excludes Price Approval.

- 1.126. "Materials" means chemical compounds, biological materials, including Clinical Trial samples, cell lines, lipids, assays, viruses and vectors, and other materials. For clarity, Materials include physical embodiments of Delivery Systems (or components thereof) and Gene Editing Systems (or components thereof).
- 1.127. "Medical Affairs Activities" means responding to external inquiries or complaints, the planning for and conduct of investigator sponsored Clinical Trials not included in a Development Plan, medical education, speaker programs, advisory boards, thought leader activities, educational grants and fellowships, local country government affairs, phase 3b Clinical Trials, generating health economics and outcomes research data from patient reported outcomes, prospective observational studies and retrospective observational studies, and economic models and reimbursement dossiers, deployment of medical science liaisons, medical affairs clinical trial management, doctors in field (other than medical science liaisons), scientific publications and medical communications.
- 1.128. "Medical Affairs Expenses" means, with respect to a Profit Share Product, all Expenses incurred by Vertex or its Affiliates in connection with the conduct of Medical Affairs Activities for such Profit Share Product, to the extent reasonably allocable to such Profit Share Product.
- 1.129. "[**]" has the meaning set forth in Section 1.133.
- 1.130. "NDA" means a new drug application that is submitted to the FDA for marketing approval for a Product, pursuant to Section 505 of the FD&C Act, or any substantially equivalent application in a jurisdiction outside the United States.
- 1.131. "**Net Loss**" means, with respect to a Profit Share Product, for a given period, Net Sales of such Profit Share Product in the Territory plus Sublicense Revenue for such Profit Share Product less Program Expenses for such Profit Share Product, where the result is a negative number.
- 1.132. "Net Profit" means, with respect to a Profit Share Product, for a given period, Net Sales of such Profit Share Product in the Territory plus Sublicense Revenue for such Profit Share Product less Program Expenses for such Profit Share Product, where the result is a positive number.
- 1.133. "Net Sales" means the [**] invoiced price for Products sold by Vertex (including sales generated from named patient programs and excluding sales deferred for GAAP accounting purposes until such sales are recognized), its Affiliates or, solely in the case of Royalty Products, Sublicensees (each, a "Selling Party") to Third Parties (including Distributors), less the following deductions from such [**] amounts:
 - (a) [**]:
 - (b) [**]

- (c) [**];
- (d) [**];
- (e) [**]; and
- (f) [**].

Only items that are deducted from the Selling Party's [**] sales of Product(s), as included in the Selling Party's published financial statements and that are in accordance with GAAP, applied on a consistent basis, will be deducted from such [**] sales for purposes of the calculation of Net Sales; *provided* that amounts written off by the Selling Party by reason of uncollectible debt pursuant to clause (a) or amounts of compulsory payments deducted pursuant to clause (f) above, respectively, may be deducted from Net Sales in accordance with clause (a) or clause (f) above, respectively, regardless of its classification in the Selling Party's published financial statements.

A qualifying amount may be deducted only once regardless of the number of the preceding categories that describes such amount. If a Selling Party makes any adjustment to such deductions after the associated Net Sales have been reported pursuant to this Agreement, the adjustments and payment of any royalties due will be reported with a subsequent quarterly report. Sales between or among Vertex, its Affiliates and, solely in the case of Royalty Products, Sublicensees will be excluded from the computation of Net Sales if such sales are not intended for end use, but Net Sales will include the subsequent final sales to Third Parties by Vertex or any such Affiliates or, solely in the case of Royalty Products, Sublicensees. A Product will not be deemed to be sold if the Product is provided free of charge to a Third Party in reasonable quantities as a sample consistent with industry standard promotional and sample practices. For clarity, Net Sales include sales such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," even if such sales occur prior to receipt of Marketing Approval.

If a sale, transfer or other disposition with respect to a Product involves consideration other than cash or is not at arm's length, the Net Sales from such sale, transfer or other disposition will be calculated based on the average Net Sales price of the Product in arm's length sales for cash in the relevant country during the same Calendar Quarter as such sale, transfer or other disposition or, in the absence of such sales, based on the fair market value of the Product as mutually determined by the Parties.

Solely for purposes of calculating Net Sales, [**] ("Other Product") (whether combined in a single formulation or package, as applicable, or formulated separately but packaged under a single label approved by a Regulatory Authority and sold together for a single price) (such combination product, a "Combination Product"), Net Sales of such Combination Product in any country for the purpose of determining the payments due to Company pursuant to this Agreement will be calculated by [**]. If the [**] selling price of the [**] in such country can be determined but the [**] selling price of the Other Product in such country cannot be determined, then Net Sales of the Combination Product in such country for purposes of determining the payments due to Company pursuant to this Agreement will be calculated by [**]. If such separate sales are not made in a country, then Net Sales of the Combination Product in such country for purposes of determining the payments due to Company pursuant to this Agreement will be calculated by [**]; provided that

if the Parties are unable to agree on such fraction, then either Party may, by written notice to the other Party, refer any such Dispute to the Executive Officers, who will confer in good faith on the resolution of the issue. Absent mutual agreement by the Executive Officers within [**] after such referral, either Party may invoke Baseball Arbitration to determine such fraction.

- 1.134. "New Company Agreement Amounts" has the meaning set forth in Section 5.7.3(a)(ii).
- 1.135. "New Company Agreement Election Notice" has the meaning set forth in Section 5.7.2(b).
- 1.136. "New Company Agreements" has the meaning set forth in Section 5.7.2(a).
- 1.137. "New In-Licensed Technology" has the meaning set forth in Section 5.7.2(a).
- 1.138. "Non-Breaching Party" has the meaning set forth in Section 9.2.2.
- 1.139. "Opt-In Information Package" means an information package for all Products, which information package includes the following information: (a) a summary of the material analyses and scientific data generated or compiled by or on behalf of Vertex with respect to Products; (b) a schedule identifying all then-known Selected Third Party Intellectual Property Costs (excluding such costs covered by clause (b) of the definition thereof) for the Products; (c) any protocols or proposed designs for anticipated Clinical Trials with respect to Products; (d) a high level summary of then-anticipated Development activities for the Products and the projected Program Expense Budget for the one year following the delivery date of the Opt-In Information Package to Company (or a longer period of time to the extent then-available); (e) [**]; and (f) a good faith estimate of all Phase 1 Preparatory Costs incurred as of the Opt-In Information Package Delivery Date.
- 1.140. "Opt-In Information Package Delivery Date" has the meaning set forth in Section 5.9.1.
- 1.141. "Opt-Out" has the meaning set forth in Section 5.9.4(a).
- 1.142. "Opt-Out Effective Date" has the meaning set forth in Section 5.9.4(a).
- 1.143. "Opt-Out Notice" has the meaning set forth in Section 5.9.4(a).
- 1.144. "Other Company Activities" has the meaning set forth in Section 2.9.1.
- 1.145. "Other Company Activities Plan" has the meaning set forth in Section 2.9.1.
- 1.146. "Other Out-of-Pocket Expenses" means, with respect to a Profit Share Product or Licensed Agent contained in a Profit Share Product, the sum of the following:
 - 1.146.1. [**];

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1.146.2. [**];
1.146.3. [**]; and
1.146.4. [**].
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- 1.147. "Other Product" has the meaning set forth in Section 1.133.
- 1.148. "Other Safety Information" means all emerging and known information about the Products involving known or potential risks to humans including: misuse, abuse, overdose, off-label use, medication error, lack of effect, suspected transmission of an infectious agent, occupational exposure, pregnancy exposure or any use of a falsified product.
- 1.149. "Out-of-Pocket Costs" means, with respect to a Party, costs and expenses paid by such Party or its Affiliates to Third Parties (or payable to Third Parties and accrued in accordance with GAAP), other than employees of such Party or its Affiliates.
- 1.150. "Overlapping Improvements" means [**].
- 1.151. "Party" or "Parties" has the meaning set forth in the Preamble.
- 1.152. "Party Specific Regulations" means all non-monetary judgments, decrees, orders or similar decisions issued by any Governmental Authority specific to a Party, and all consent decrees, corporate integrity agreements, or other agreements or undertakings of any kind by a Party with any Governmental Authority, in each case as the same may be in effect from time to time and applicable to a Party's activities contemplated by this Agreement.
- 1.153. "Patent Enforcement Expenses" means, with respect to a Profit Share Product or Licensed Agent contained in a Profit Share Product, all Expenses incurred by either Party or its respective Affiliates, (a) for the enforcement of Patents that Cover such Profit Share Product or Licensed Agent and (b) that are not reimbursed pursuant to Section 6.4.4(a).
- 1.154. "Patents" means the rights and interests in and to issued patents and pending patent applications in any country, jurisdiction or region (including inventor's certificates and utility models), including all provisionals, non-provisionals, substitutions, continuations, continuations-in-part, divisionals, renewals and all patents granted thereon, and all reissues, reexaminations, extensions, confirmations, revalidations, registrations and patents of addition thereof, including patent term extensions and supplementary protection certificates, international patent applications filed under the Patent Cooperation Treaty (PCT) and any foreign equivalents to any of the foregoing.
- 1.155. "Payee" has the meaning set forth in Section 5.11.1.
- 1.156. "Payment" has the meaning set forth in Section 5.11.1.

- 1.157. "Payor" has the meaning set forth in Section 5.11.1.
- 1.158. "Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision or department or agency of a government.
- 1.159. "**Phase 1 Clinical Trial**" means any Clinical Trial as described in 21 C.F.R. §312.21(a), or, with respect to a jurisdiction other than the United States, an equivalent Clinical Trial.
- 1.160. "**Phase 3 Clinical Trial**" means any Clinical Trial as described in 21 C.F.R. §312.21(c), or, with respect to a jurisdiction other than the United States, an equivalent Clinical Trial.
- 1.161. "Phase 1 Preparatory Costs" means the [**].
- 1.162. "Pivotal Clinical Trial" means, with respect to a Product, a Clinical Trial in humans performed to gain evidence with statistical significance of the efficacy of such Product in a target population, and to obtain expanded evidence of safety for such Product that is needed to evaluate the overall benefit-risk relationship of such Product, to form the basis for filing an Approval Application and obtaining Marketing Approval from a Regulatory Authority for such Product and to provide an adequate basis for physician labeling. If a Clinical Trial is not a Pivotal Clinical Trial on its Initiation but later meets the requirements of a Pivotal Clinical Trial, then such Clinical Trial shall be considered a Pivotal Clinical Trial on the Initiation of the portion of the Clinical Trial that satisfies the requirements for a Pivotal Clinical Trial.
- 1.163. "Pre-Approved Subcontractors" has the meaning set forth in Section 2.1.7.
- 1.164. "**Price Approval**" means, in any country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination.
- 1.165. "**Proceeding**" means any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), prosecution, contest, hearing, inquiry, inquest, audit, examination or investigation that is, has been or may in the future be commenced, brought, conducted or heard at law or in equity or before any Governmental Authority.
- 1.166. "**Product**" means any product containing a Licensed Agent, in any form or formulation, and whether alone or together with one or more other therapeutically active ingredients, Delivery Systems or other components.

- 1.167. "Product Advancement Date" has the meaning set forth in Section 2.1.8.
- 1.168. "**Profit Share Effective Date**" has the meaning set forth in Section 5.9.2.
- 1.169. "Profit Share Exercise Notice" has the meaning set forth in Section 5.9.2.
- 1.170. "**Profit Share Option**" has the meaning set forth in Section 5.9.2.
- 1.171. "**Profit Share Split**" means, as elected by Company in accordance with Section 5.9.2 and subject to Section 5.9.4(b), either (a) 60% Vertex and 40% Company or (b) [**]% Vertex and [**]% Company.
- 1.172. "**Profit Share Split Step-Down**" has the meaning set forth in Section 5.9.4(b).
- 1.173. "Profit Share Split Step-Down Effective Date" has the meaning set forth in Section 5.9.4(b).
- 1.174. "Profit Share Split Step-Down Notice" has the meaning set forth in Section 5.9.4(b).
- 1.175. "**Profit Share Products**" means all Products on and after the Profit Share Effective Date but prior to the Opt-Out Effective Date. For clarity, "Profit Share Product" means any Product on and after the Profit Share Effective Date but prior to the Opt-Out Effective Date.
- 1.176. "Program Expense Budget" has the meaning set forth in Section 5.9.5(b).
- 1.177. "**Program Expenses**" means, with respect to a Profit Share Product, [**].
- 1.178. "Prosecution and Maintenance" or "Prosecute and Maintain" means, with regard to a Patent, the preparing, filing, prosecuting and maintenance of such Patent, as well as handling re-examinations and reissues with respect to such Patent, together with the conduct of interferences, derivation proceedings, the defense of oppositions, post-grant patent proceedings (such as inter partes review and post grant review) and other similar proceedings with respect to the particular Patent. For clarification, "Prosecution and Maintenance" or "Prosecute and Maintain" will not include any other enforcement actions taken with respect to a Patent.
- 1.179. "Receiving Party" has the meaning set forth in Section 10.1.
- 1.180. "**Reconciliation Report**" has the meaning set forth in Section 5.9.9(a).
- 1.181. "Regulatory Approval" means the technical, medical and scientific licenses, registrations, authorizations, clearances, accreditations and approvals (including approvals of Approval Applications, supplements and amendments, pre- and post- approvals, and labeling approvals) of any Regulatory Authority, necessary for the research, development, clinical testing, commercial manufacture, distribution, marketing, promotion, offer for sale, use, import, export or sale of a pharmaceutical

- product in a regulatory jurisdiction, including Marketing Approval but excluding Price Approval.
- 1.182. "Regulatory Authority" means, with respect to a country in the Territory, any national (e.g., the FDA), supranational (e.g., the European Commission, the Council of the European Union, or the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority involved in the granting of Regulatory Approvals or Price Approvals for pharmaceutical products in such country or countries.
- 1.183. "Regulatory Filings" means, collectively: (a) all (i) INDs or other filings needed to initiate clinical testing of any pharmaceutical product, (ii) Approval Applications (including BLAs and NDAs), establishment license applications and drug master files, (iii) applications for designation as an "Orphan Product(s)" under the Orphan Drug Act, (iv) applications for "Fast Track" status, "Breakthrough Therapy" status or "Regenerative Medicine Advanced Therapy Designation" under Section 506 of the FD&C Act (21 U.S.C. § 356) or (v) requests for a Special Protocol Assessment under Section 505(b)(4)(B) and (C) of the FD&C Act (21 U.S.C. § 355(b)(4)(B)) and all other similar filings (including counterparts of any of the foregoing in any country or region in the Territory); (b) any applications for Regulatory Approval or Price Approval and other applications, filings, dossiers or similar documents submitted to a Regulatory Authority in any country for the purpose of obtaining Regulatory Approval or Price Approval from that Regulatory Authority; (c) any supplements and amendments to any of the foregoing; and (d) any correspondence with any Regulatory Authority relating to any of the foregoing.
- 1.184. "Relevant Confidential Information" has the meaning set forth in Section 4.6.
- 1.185. "**Reported Amounts**" has the meaning set forth in Section 5.12.2.
- 1.186. "Required Withholding" has the meaning set forth in Section 5.11.1.
- 1.187. "Research" means, with respect to a Product or Licensed Agent contained in a Product, conducting research activities to discover, design, optimize, deliver and advance such Licensed Agent or Product, including preclinical studies and optimization up to the filing of an IND for any such Product, but excluding, Development, Manufacture and Commercialization. When used as a verb, "Researching" means to engage in Research.
- 1.188. "Research Activities" has the meaning set forth in Section 2.1.1.
- 1.189. "Research Budget" has the meaning set forth in Section 2.1.1.
- 1.190. "Research Plan" has the meaning set forth in Section 2.1.1.
- 1.191. "**Research Term**" means the period beginning on the Effective Date and ending on the fourth anniversary of the Effective Date, subject to any extension pursuant to Section 2.1.5.

- 1.192. "Research Term Extension Notice" has the meaning set forth in Section 2.1.5.
- 1.193. "Residual Knowledge" means knowledge, techniques, experience and Know-How that are (a) reflected in any Confidential Information owned or controlled by the Disclosing Party and (b) retained in the unaided memory of any authorized representative of the Receiving Party after having access to such Confidential Information. A Person's memory will be considered to be unaided if the Person has not intentionally memorized the Confidential Information for the purpose of retaining and subsequently using or disclosing it.
- 1.194. "Royalty-Bearing Vertex System Patent" means any Vertex System Patent that claims or covers Vertex System Know-How that was Created solely or jointly by Company or its Affiliates or Third Parties acting on its or their behalf, in each case, in the performance of Agreement Activities.
- 1.195. "Royalty Product" means any Product other than a Profit Share Product.
- 1.196. "Royalty Report" has the meaning set forth in Section 5.5.7.
- 1.197. "Royalty Term" means, with respect to a Royalty Product in a country, the period commencing on the first sale of such Royalty Product giving rise to Net Sales in such country and ending upon the latest of: (a) the expiration of the last Valid Claim of a Licensed Patent or Royalty-Bearing Vertex System Patent that Covers such Product in such country; (b) 10 years after the First Commercial Sale of such Product in such country; or (c) expiration of all applicable regulatory exclusivity periods, including data exclusivity, in such country with respect to such Product.
- 1.198. "Rules" has the meaning set forth in Section 11.12.3(a).
- 1.199. "Safety Data Exchange Agreement" has the meaning set forth in Section 2.8.
- 1.200. "Selected Third Party Intellectual Property" means, with respect to a Licensed Agent or Product, Patents or Know-How owned or controlled by a Third Party (but not then included in Licensed Technology) that Cover (with respect to Patents) or are necessary or reasonably useful to Research, Develop, Manufacture or Commercialize (with respect to Know-How) such Licensed Agent or Product.
- 1.201. "Selected Third Party Intellectual Property Costs" means: (a) Out-of-Pocket Costs, including upfront payments, purchase price, milestones, royalties, license fees, option fees, option exercise fees and other payments paid by Vertex or its Affiliates or Sublicensees to a Third Party that owns or controls Selected Third Party Intellectual Property (or that, prior to the applicable transaction with Vertex or its Affiliates or Sublicensees, owned or controlled Selected Third Party Intellectual Property) to license or acquire such Selected Third Party Intellectual Property; provided that, if the applicable Selected Third Party Intellectual Property relates to both a Licensed Agent or Product and one or more other programs of Vertex or its Affiliates or Sublicensees, then any such Out-of-Pocket Costs that are not specific to the Research, Development, Manufacturing or Commercialization

of a Licensed Agent or Product (*e.g.*, upfront payments, purchase price, etc.) shall be equitably allocated by Vertex among the applicable Licensed Agent or Product and such other programs, and only such portion that is allocated to the applicable Licensed Agent or Product shall constitute Selected Third Party Intellectual Property Costs; and (b) any royalty or other payment obligation under a Company In-License Agreement that is deemed to be a Selected Third Party Intellectual Property Cost as set forth in Section 5.7.3(a).

- 1.202. "Selling Party" has the meaning set forth in Section 1.133.
- 1.203. "[**]" means [**].
- 1.204. "SPA" has the meaning set forth in Section 5.2.
- 1.205. "**Subcontractor**" has the meaning set forth in Section 2.1.7.
- 1.206. "Sublicense" means, when used as a verb, directly or indirectly, to sublicense under, grant any other right with respect to, or agree not to assert, any rights granted to Vertex under Section 4.1.1(a). When used as a noun, "Sublicense" means any agreement to Sublicense.
- 1.207. "**Sublicensee**" means a Third Party, other than a service provider or Distributor, to whom Vertex (or a Sublicensee or Affiliate) sublicenses any of the rights granted to Vertex under Section 4.1.1(a) during the Term.
- 1.208. "Sublicense Revenue" means, with respect to a Profit Share Product, [**].
- 1.209. "Summary Statement" has the meaning set forth in Section 5.9.8.
- 1.210. "Tax Action" has the meaning set forth in Section 5.11.3.
- 1.211. "**Term**" has the meaning set forth in Section 9.1.
- 1.212. "Territory" means worldwide.
- 1.213. "Third Party" means any Person other than Vertex, Company or their respective Affiliates.
- 1.214. "**Third Party Claim**" has the meaning set forth in Section 8.1.1.
- 1.215. "Third Party Infringement Claim" has the meaning set forth in Section 6.3.
- 1.216. "Transferee Party" has the meaning set forth in Section 2.1.10.
- 1.217. "Transferor Party" has the meaning set forth in Section 2.1.10.
- 1.218. "**Type 1 Product**" means any Product containing [**]. All Type 1 Products comprising [**] will be considered the same Type 1 Product under this Agreement.

- 1.219. "Type 2 Product" means any Product containing [**]. All Type 2 Products comprising [**].
- 1.220. "United States" or "U.S." means the United States of America and all of its districts, territories and possessions.
- 1.221. "Valid Claim" means a claim (a) of any issued, unexpired United States or foreign Patent, which has not, in the country of issuance, been donated to the public, disclaimed, or held invalid or unenforceable by a court of competent jurisdiction in an unappealed or unappealable decision, or (b) of any United States or foreign patent application, which has not, in the country in question, been cancelled, withdrawn, or abandoned. Notwithstanding the foregoing, on a country-by-country basis, a patent application pending for more than [**] from the earliest priority date with respect thereto will not be considered to have any Valid Claim for purposes of this Agreement unless and until a patent that meets the criteria set forth in clause (a) above with respect to such application issues.
- 1.222. "Vertex" has the meaning set forth in the Preamble.
- 1.223. "Vertex Agreement Know-How" means Know-How, other than Company System Know-How, that is Created solely by Vertex or its Affiliates or Third Parties acting on its or their behalf, in each case, in the performance of Agreement Activities.
- 1.224. "Vertex Agreement Patents" means Patents that claim any Vertex Agreement Know-How and do not claim Company Agreement Know-How, Joint Agreement Know-How or Company System Know-How.
- 1.225. "Vertex Agreement Technology" means the Vertex Agreement Know-How and Vertex Agreement Patents.
- 1.226. "Vertex Amounts" has the meaning set forth in Section 5.7.3(a)(i)(A).
- 1.227. "Vertex Delivery System" means any Delivery System that: (a) is, in whole or in part, Covered by any Patent Controlled by Vertex or any of its Affiliates; or (b) incorporates or embodies any Know-How Controlled by Vertex or any of its Affiliates.
- 1.228. "Vertex Gene Editing System" means any Gene Editing System that: (a) is, in whole or in part, Covered by any Patent Controlled by Vertex or any of its Affiliates; or (b) incorporates or embodies any Know-How Controlled by Vertex or any of its Affiliates.
- 1.229. "Vertex Indemnified Party" has the meaning set forth in Section 8.1.2.
- 1.230. "Vertex Research Expenses" means, with respect to a Profit Share Product, all Expenses incurred by Vertex and its Affiliates in connection with Research of such

Profit Share Product, to the extent reasonably allocable to such Profit Share Product (including the Licensed Agent in such Profit Share Product).

- 1.231. "Vertex System Know-How" means any Know-How, other than any Know-How that constitutes an Overlapping Improvement, that is Created in the performance of Agreement Activities either (a) solely by Company or its Affiliates or Third Parties acting on its or their behalf, (b) jointly by both Parties or their respective Affiliates or Third Parties acting on their behalf or (c) solely by Vertex or its Affiliates or Third Parties acting on its behalf, in each case ((a)-(c)), solely to the extent that such Know-How: [**].
- 1.232. "Vertex System Patents" means Patents that claim any Vertex System Know-How and do not claim Company Agreement Know-How, Joint Agreement Know-How, Company System Know-How or Overlapping Improvements.
- 1.233. "Vertex System Technology" means the Vertex System Know-How and Vertex System Patents.
- 1.234. "[**]" has the meaning set forth in <u>Schedule 1.234</u>.
- 1.235. "[**]" has the meaning set forth in Schedule 1.235.

ARTICLE 2. RESEARCH, DEVELOPMENT, MANUFACTURING AND COMMERCIALIZATION

2.1. Research.

- 2.1.1. **Research Plan & Budget**. The initial research plan is set forth in Schedule 2.1.1 (such plan, as may be amended pursuant to Section 2.1.3, the "Research Plan"). The activities relating to the Research of Licensed Agents and Products will be conducted by the Parties under this Agreement during the Research Term in accordance with the Research Plan (such activities, the "Research Activities"); provided that Vertex shall have the right to Research any Licensed Agent outside of the Research Plan any time after the occurrence of the Product Advancement Date, including during the Research Term. The initial Research Plan includes a budget for the Research Activities to be conducted by Company from the Effective Date through [**] (such budget, as amended from time to time (including to reflect Research Activities to be conducted by Company after [**]), the "Research Budget"). The Research Plan (including the Research Budget) may be amended as set forth in this Agreement. The Research Budget may include stage gating with respect to certain amounts to allow the JRC to determine from time to time whether to progress with the applicable Research Activities prior to commencement of such activities.
- 2.1.2. **Research Objectives.** Company's Research Activities in the Research Plan shall be focused on [**]. Vertex [**] and may contribute Vertex

Delivery Systems or Vertex Gene Editing Systems for use in the Research Activities, in each case, as determined by Vertex in its sole discretion.

- 2.1.3. Amendments to Research Plan and Budget. Within [**] after the Effective Date (or such longer period as determined by the JRC), the JRC will review and amend the initial Research Plan to add additional details regarding the Research Activities. In addition, during the Research Term, the Research Plan (including the Research Budget) will be reviewed at least [**] by the JRC (and in any event, at least [**] prior to expiration of the period covered by the then-current Research Budget) and the JRC shall amend the Research Plan (including the Research Budget) during such review as is appropriate to (a) reflect any material developments and adjustments to the planned Research Activities (and, for clarity, the introduction into or removal from the Research Plan of a Gene Editing System or Delivery System will constitute a material development or adjustment) and (b) determine the Research Budget for the [**] subsequent to the period covered by the then-current Research Budget (provided that the Parties intend to include the budget for the period starting [**] and ending [**] in the same Research Budget and, thereafter, determine the Research Budget on a [**] basis). In addition, the JRC may amend the Research Plan (including the Research Budget) at any time during the Research Term to reflect material developments and adjustments to the Research of Licensed Agents and Products, including to increase or decrease the Research Budget to account for changes in the Research Activities.
- 2.1.4. Conduct of the Research. Each Party, directly or through its Affiliates or permitted Subcontractors, will use Commercially Reasonable Efforts to conduct the activities allocated to it in the Research Plan in accordance with the Research Plan, including the timelines set forth therein, and in a professional and timely manner. Each Party will, and will require its Affiliates and Subcontractors to, perform its obligations under the Research Plan in compliance with Applicable Law. Except as otherwise set forth in the Research Plan, Company will be solely responsible for conducting all Research Activities. Vertex shall reimburse Company in accordance with Section 5.8 for Company's FTE Costs and Out-of-Pocket Costs incurred in conducting such Research Activities in accordance with the Research Plan (including the Research Budget).
- 2.1.5. **Extension of the Research Term**. Vertex shall have the one-time right, upon written notice to Company prior to the expiration of the Research Term, to extend the Research Term for an additional one-year period (such notice, the "**Research Term Extension Notice**"). Within [**] after delivering the Research Term Extension Notice, Vertex shall pay Company an amount of \$[**] in consideration for the extension of the Research Term.

2.1.6. Additional Research.

- Following the Research Term, upon Vertex's request for Company to conduct certain (a) additional Research activities with respect to Licensed Agents or Products, the Parties shall discuss in good faith and, (subject to Section 2.1.6(b)) if the Parties agree that Company will conduct such activities, agree on a plan (each, an "Additional Research Plan") and budget (each, an "Additional Research Budget") for such activities (the "Additional Research Activities"). If the Parties agree on the Additional Research Plan and Additional Research Budget, then Company, directly or through its Affiliates or permitted Subcontractors, will use Commercially Reasonable Efforts to conduct the Additional Research Activities in accordance with the Additional Research Plan, including the timelines set forth therein, and in a professional and timely manner. Company will, and will require its Affiliates and Subcontractors to, perform its obligations under the Additional Research Plan in compliance with Applicable Law. Vertex shall reimburse Company in accordance with Section 5.8 for Company's FTE Costs and Out-of-Pocket Costs incurred in conducting such Additional Research Activities in accordance with the Additional Research Plan and Additional Research Budget. The Parties may amend any Additional Research Plan and Additional Research Budget upon mutual consent.
- (b) Notwithstanding Section 2.1.6(a), if Vertex desires for Company to conduct additional Research activities with respect to any Licensed Agent or Product in order to ensure that (i) Patents or Know-How Controlled by Company or its Affiliates pursuant to a Company In-License Agreement are included within the Licensed Technology or (ii) such Licensed Agent or Product is included within the scope of the rights granted under any Company In-License Agreement, then, in each case ((i) or (ii)), Company shall conduct such activities pursuant to an Additional Research Plan and Additional Research Budget that shall be agreed on by the Parties in good faith and, for clarity, the other terms and conditions of this Agreement shall apply with respect to the applicable Additional Research Plan, Additional Research Budget and Additional Research Activities.
- 2.1.7. **Subcontracting**. Each Party may engage consultants, subcontractors, academic researchers or other vendors (each, a "**Subcontractor**") to perform Research Activities allocated to such Party under the Research Plan or Additional Research Activities allocated to such Party under the Additional Research Plan, as applicable; *provided that* Company shall obtain Vertex's prior written consent for the performance of any Research Activities: (a) by any Subcontractor headquartered outside of the U.S. or Europe; (b) by any Subcontractor performing the Research Activities

outside of the U.S. or Europe; or (c) by any Subcontractor that is a nonprofit entity (e.g., a university) or employee of a nonprofit entity, except that, in each case ((a)-(c)), such consent shall not be required with respect to those pre-approved Subcontractors forth in Schedule 2.1.7 (such Subcontractors, "Pre-Approved Subcontractors"). Without limiting the foregoing, in the event Company desires to engage a Subcontractor that requires Vertex's approval, Company shall provide notice thereof to Vertex and Vertex shall have the right to respond within [**]. If Vertex does not respond within such [**] period, the Subcontractor proposed by Company will be deemed to be approved. Each contract between a Party and a Subcontractor shall include (i) confidentiality provisions that are at least as restrictive as those described in ARTICLE 10 except with respect to the duration of such obligations which will be commercially reasonable and customary for agreements of the applicable type and (ii) intellectual property provisions that will enable the subcontracting Party to grant the licenses and assignments granted in this Agreement. Each Party shall be responsible for the effective and timely management of and payment of its Subcontractors. The engagement of any Subcontractor in compliance with this Section 2.1.7 shall not relieve the applicable Party of its obligations under this Agreement.

- 2.1.8. **Records**. Each Party shall maintain, and cause its Affiliates and Subcontractors to maintain, records of its activities under the Research Plan or Additional Research Plan in sufficient detail and in good scientific manner appropriate for scientific, patent and regulatory purposes, which shall be complete and accurate in all material respects and shall fully and properly reflect all work done, data and developments made, and results achieved. On and after the earlier of (a) the date of [**] with respect to any Product and (b) the date that [**] with respect to any Product (the earlier of (a) and (b), the "**Product Advancement Date**"), Vertex will have the right, upon reasonable prior notice and during normal business hours, to access, review and copy the records of Company's and its Affiliates' and Subcontractors' activities under the Research Plan or Additional Research Plan with respect to the applicable Product and any Licensed Agent contained in such Product, including laboratory notebooks and raw data.
- 2.1.9. **Progress Reports**. During the Research Term, each Party shall furnish to the JRC, within [**] after the end of each [**], an update on such Party's progress under the Research Plan with respect to the performance of the Research Activities during the relevant [**], including a summary of any results and data generated by or on behalf of such Party or its Affiliates under the Research Plan during the relevant [**]. For so long any Additional Research Plan is in effect, Company shall furnish to Vertex, within [**] after the end of each [**], an update on Company's progress under the Additional Research Plan with respect to the performance of the

Additional Research Activities during the relevant [**], including a summary of any results and data generated by or on behalf of Company or its Affiliates under the Additional Research Plan during the relevant [**].

- 2.1.10. Transfer of Materials. To facilitate the conduct of activities under the Research Plan or an Additional Research Plan, as applicable, either Party (the "Transferor Party") may, at its election, provide Materials to the other Party (the "Transferee Party") solely as mutually agreed by the Parties (including as set forth in the Research Plan or Additional Research Plan). All such Materials (a) will remain the sole property of the Transferor Party. (b) will be used only in the exercise of the Transferee Party's rights or fulfillment of the Transferee Party's obligations under this Agreement, (c) except as provided in the Research Plan or Additional Research Plan, or otherwise agreed by Transferor Party in writing, (i) will remain solely under the control of the Transferee Party, (ii) will not be used or delivered by the Transferee Party to or for the benefit of any Third Party and (iii) will not be used in research or testing involving human subjects, and (d) will be subject to all additional restrictions and obligations that the Transferor Party has identified in a written notice to the Transferee Party as being necessary for the Transferor Party to comply with its obligations to Third Parties with respect to the applicable Material, which notice is provided at or prior to the delivery of such Materials to the Transferee Party. Without limitation to ARTICLE 7, all Materials supplied under this Section 2.1.10 are supplied "as is", with no warranties of fitness for a particular purpose, and must be used with prudence and appropriate caution in any experimental work, as not all of their characteristics may be known. Except in the case of Vertex as the Transferee Party with respect to any Materials provided by Company that Vertex has the right to Exploit under the license granted in Section 4.1.1(a), following the completion of the activities for which the applicable Materials were supplied under this Section 2.1.10 or upon the Transferor Party's earlier request, the Transferee Party shall either destroy or return to the Transferor Party, at the Transferor Party's sole discretion, all Materials provided by the Transferor Party that are unused.
- 2.1.11. **Research Following Research Term.** Following the Research Term, subject to Section 2.6, Vertex will have the sole and exclusive control over all matters relating to the Research of Licensed Agents and Products. Subject to Section 11.2.2, for so long as Vertex is conducting Research activities under this Section 2.1.11, no later than [**] of each Calendar Year, Vertex will provide Company with a high-level report regarding the status of such Research of Licensed Agents and Products. Such reports may be combined with any applicable reports under Section 2.2.2 and may be provided to Company in conjunction with meetings and other communications between the representatives of Vertex and Company on the JRC (or the JSC, if the JRC has been discontinued pursuant to Section

3.1.5). At Company's reasonable request, Vertex will meet with Company following delivery of any such report to discuss with Company the contents thereof and Company's questions with respect thereto.

2.2. **Development**.

- 2.2.1. **Generally**. Subject to Section 2.6, Vertex will have sole and exclusive control over all matters relating to the Development of Licensed Agents and Products.
- 2.2.2. **Reporting**. Subject to Section 11.2.2, for so long as Vertex is conducting Development activities with respect to Licensed Agents or Products, no later than [**] of each Calendar Year, Vertex will provide Company with a high-level report regarding the status of such Development of Licensed Agents and Products. Such reports may be provided to Company in conjunction with meetings and other communications between the representatives of Vertex and Company on the JSC. At Company's reasonable request, Vertex will meet with Company following delivery of any such report to discuss with Company the contents thereof and Company's questions with respect thereto.

2.3. Regulatory Matters.

- 2.3.1. **Responsibilities**. Subject to Section 2.6, Vertex will have the sole and exclusive authority to (a) prepare and file Regulatory Filings and applications for Price Approval, each in its own name (or in the name of its designee(s)), for all Licensed Agents and Products in the Field in the Territory, and (b) communicate with Regulatory Authorities with respect to the Licensed Agents and Products in the Field in the Territory, both prior to and following Marketing Approval and Price Approval, including all communications and decisions with respect to (i) labeling of Products, and (ii) the negotiation of Price Approvals. Without limiting the foregoing, during the Term, neither Company nor its Affiliates will prepare or file any Regulatory Filings with any Regulatory Authority with respect to any Licensed Agent or Product in the Field in the Territory.
- 2.3.2. **Ownership**. Ownership of all right, title and interest in and to all Regulatory Filings, Regulatory Approvals and Price Approvals directed to any Licensed Agent or Product in the Field in each country of the Territory will be held by and in the name of Vertex, its Affiliate, designee or Sublicensee.
- 2.3.3. **Cooperation**. Company will, and will cause its Affiliates to reasonably cooperate with Vertex with respect to all regulatory matters relating to any Licensed Agent or Product. Without limiting the foregoing, as requested by Vertex, Company will provide reasonable assistance to Vertex in preparing Regulatory Filings for Products and make information

controlled by Company or its Affiliates available to Vertex to the extent reasonably necessary in connection with such Regulatory Filings. Upon Vertex's reasonable request, Company will provide reasonable support to Vertex for the Development of Licensed Agents and Products by providing Regulatory Authorities with access to, and the right to audit, any data or other Know-How and associated documents that are in Company's possession or control and are relied on by Vertex in its Regulatory Filings for Licensed Agents and Products. Vertex will reimburse Company for its reasonable Expenses incurred in conducting the foregoing activities. Company shall submit an invoice to Vertex setting forth Company's reasonable Expenses incurred in conducting such activities and Vertex will pay such invoice within [**] after receipt thereof. Company will not make any submission to any Regulatory Authority with respect to the Licensed Agents and Products in the Field in the Territory without first obtaining Vertex's prior written consent.

- 2.3.4. **Right of Reference**. Company hereby grants Vertex, its Affiliates and designees, Sublicensees and Distributors a "Right of Reference" (including rights of reference or cross-reference as discussed in FDA's regulations (see 21 C.F.R. §§ 312.23(b), 314.3(b), 601.51(a)) and any foreign counterparts to such regulations), to any Regulatory Filings Controlled by Company or its Affiliates that are necessary or reasonably useful to Exploit a Licensed Agent or Product in the Field in the Territory solely for the purpose of Exploiting such Licensed Agent or Product in the Field in the Territory. If requested by Vertex, Company will provide a signed statement to this effect (including a statement of right of reference that can be submitted to module 1 of a Regulatory Filing of Vertex).
- 2.4. <u>Manufacturing</u>. Following the Research Term, Vertex will have sole and exclusive control over all matters relating the Manufacture and supply of Licensed Agents and Products for Exploitation in the Field in the Territory.

2.5. **Commercialization**.

- 2.5.1. **General**. Subject to Section 2.6, Vertex will have sole and exclusive control over all matters relating to the Commercialization of Products in the Field in the Territory.
- 2.5.2. **Branding**. Vertex will have sole and exclusive control over all matters relating to the selection of all trademarks used in connection with the Commercialization of any Product in the Field in the Territory and Vertex or its designee(s) shall own all of such trademarks. Company will not use nor seek to register, anywhere in the Territory, any trademark that is confusingly similar to any trademark used by or on behalf of Vertex, its Affiliates or Sublicensees in connection with any Product.

- 2.6. <u>Vertex Diligence</u>. Following the Research Term, Vertex (acting directly or through one or more Affiliates or Sublicensees) will use Commercially Reasonable Efforts to (a) [**] and (b) [**].
- 2.7. <u>Applicable Law</u>. Vertex will, and will require its Affiliates and Sublicensees to, comply in all material respects with Applicable Law in its and their Research, Development, Manufacture and Commercialization of Licensed Agents and Products, including, where required, GMP, GCP and GLP.
- 2.8. Safety Data Exchange. Upon Vertex's request, the Parties will negotiate and enter into a separate safety data exchange agreement (a "Safety Data Exchange Agreement"). The Safety Data Exchange Agreement will set forth guidelines and procedures for the receipt, investigation, recording, review, communication, reporting and exchange between the Parties of Adverse Event reports and Other Safety Information, that, for purposes of information exchange between the Parties, will include Adverse Events and serious Adverse Events, and any other information concerning or impacting the safety of any Product or Licensed Agent. Without limiting the foregoing, upon Vertex's request, the Parties will meet to establish a safety oversight working group comprised of members of both Parties, which, except as otherwise provided in the Safety Data Exchange Agreement, will discuss and establish processes and procedures for sharing information needed to support each Party's regulatory responsibilities and to comply with applicable regulatory pharmacovigilance requirements. Any such procedures will not be construed to restrict either Party's ability to take any action that it deems to be appropriate or required of it under the applicable regulatory requirements, if permitted by Applicable Law. Without limiting the foregoing: (a) Company will promptly disclose to Vertex in writing any information in Company's possession regarding the occurrence of any Adverse Event or any Other Safety Information, in each case, that may reasonably relate to the safety of a Product or Licensed Agent and (b) Vertex will promptly disclose to Company in writing any information in Vertex's possession regarding the occurrence of any Adverse Event or any Other Safety Information, in each case, that may reasonably relate to the safety of a Product or Licensed Agent and that Vertex believes in good faith relates to a Company Delivery System or Company Gene Editing System and not specifically to a Licensed Agent or Product. In addition, Vertex will (i) maintain a unified worldwide Adverse Event database for Products, and be responsible for reporting Adverse Events and serious Adverse Events to the applicable Regulatory Authorities and (ii) be responsible for all signal detection and risk management activities with respect to Products and will develop and approve the contents of all safety communications to Regulatory Authorities, including expedited non-clinical and clinical safety reports and aggregate reports to health authorities, institutional review boards and ethics committees.

2.9. Other Company Activities.

2.9.1. **Other Company Activities Plan**. Notwithstanding anything to the contrary in this Agreement, the Parties may from time to time decide by

mutual agreement to allocate to Company or its Affiliates certain Research, Development, Manufacturing or Commercialization activities with respect to one or more Profit Share Products. Any such agreement will be set forth in a written plan duly executed by both Parties (each such plan, an "Other Company Activities Plan", and activities conducted by Company or its Affiliates pursuant to such Other Company Activity Plan(s), "Other Company Activities"). Each Other Company Activities Plan will include a budget setting forth Expenses for the Other Company Activities thereunder.

- 2.9.2. **Diligence**. Subject to Section 11.2.2, Company, itself or through its Affiliates, will use Commercially Reasonable Efforts to conduct the Other Company Activities in accordance with the timelines set forth in the applicable Other Company Activities Plan. Company and its Affiliates will conduct their activities in compliance with Applicable Law.
- 2.9.3. **Reporting**. Company will provide the JSC with reasonably detailed summary updates regarding the progress of Other Company Activities, if any, at each JSC meeting.

ARTICLE 3. GOVERNANCE

3.1. **Joint Research Committee**.

3.1.1. **Formation**. Within [**] after the Effective Date, the Parties will establish a joint research committee (the "JRC"). The JRC will be composed of [**] from each Party or such other equal number of representatives from each Party as the JRC may from time to time agree. Each Party's representatives on the JRC shall be of the seniority and experience appropriate in light of the functions, responsibilities and authority of the JRC. In addition, each Party may invite a reasonable number of additional representatives to participate in discussions and meetings of the JRC in a non-voting capacity. Each Party's representatives on the JRC and all other individuals participating in discussions and meetings of the JRC on behalf of a Party will be subject to confidentiality and non-use obligations with respect to information disclosed at such meeting that are no less restrictive than the provisions of ARTICLE 10 except with respect to the duration of such obligations which will be commercially reasonable. [**] will designate the chairperson of the JRC. The chairperson of the JRC will be responsible for setting the agenda for meetings of the JRC with input from the other members, and for conducting the meetings of the JRC. The JRC will conduct its responsibilities hereunder in good faith and with reasonable care and diligence.

3.1.2. **Responsibilities**. The JRC will:

- (a) provide a forum for the Parties to discuss the progress of the Research Activities and address issues and share information relating thereto;
- (b) review, consider and select, from time to time, Gene Editing Systems and Delivery Systems for inclusion in or exclusion from Licensed Agents and Products, including Licensed Agents and Products tested in *in vivo* studies under the Research Plan;
- (c) review, consider for approval, and if so determined, approve, each amendment to the (i) Research Plan (including the Research Budget) and (ii) [**];
- (d) review all material Research Activities undertaken by or on behalf of the Parties under the Research Plan, including the exchange and review of data and information generated pursuant to the Research Plan;
- (e) oversee and coordinate the transfer of Licensed Technology to Vertex;
- (f) facilitate the sharing of Research reports in accordance with Section 2.1.11; and
- (g) perform such other duties as are specifically assigned to the JRC under this Agreement.

3.1.3. **Meetings; Minutes**.

- (a) The JRC will meet in person or by teleconference at least [**] on such dates and at such times and places as agreed to by the members of the JRC; *provided* that at least [**] shall be in person unless the Parties agree otherwise. Notwithstanding anything to the contrary in this Agreement, each Party will be responsible for its own expenses relating to attendance at, or participation in, JRC meetings.
- (b) The Alliance Managers will provide the members of the JRC with draft written minutes for approval from each meeting within [**] after each such meeting. The responsibility for preparing the minutes will alternate between the Alliance Managers on a meeting-by-meeting basis. If the minutes of any meeting of the JRC are not approved by the JRC (with each Party's representatives on the JRC collectively having one vote and without regard to the decision-making procedure set forth in Section 3.1.4) within [**] after the meeting, the objecting Party will append a notice of objection with the specific details of the objection to the proposed minutes.

- 3.1.4. Decision-Making. Each Party's representatives on the JRC will collectively have one vote on all matters within the scope of the JRC's responsibilities. The JRC members will use reasonable efforts to reach agreement on all JRC matters. If the JRC is unable to reach agreement with respect to a particular matter for which it is responsible within [**] after the matter is first presented to the JRC, the matter will be referred to the Executive Officers, who will use reasonable efforts to reach agreement on such matter. If such Executive Officers are unable to reach agreement with respect to a particular matter within [**] after the matter is first referred to such Executive Officers, subject to Section 3.1.5, (a) [**] will have the right to make the final decision with respect to such matter, [**], and (b) except as provided in the foregoing clause (a), [**] will have the right to make the final decision with respect to such matter (including, for clarity, with respect to: [**]; provided that the Party with final decision making authority (i) will take into reasonable consideration the recommendations and concerns raised by the other Party. (ii) will make such decisions in good faith using reasonable business judgment, which will not be unreasonably delayed and (iii) will not have the right to: (A) amend, modify or waive compliance with any term or condition of this Agreement; (B) make any decision that is expressly stated in this Agreement to require the mutual agreement of the Parties; (C) resolve any claim or dispute regarding the interpretation of this Agreement, including whether or in what amount a payment is owed under this Agreement or whether a Party is in breach of this Agreement; (D) exercise its final decision-making authority in a manner that would require the other Party to perform any act that the other Party reasonably believes would violate Applicable Law or any Third Party contractual obligations of such Party; or (E) (in the case of [**] as the Party with final decision-making authority) amend or modify [**], if such amendment or modification would [**]; provided that [**].
- 3.1.5. **Discontinuation of the JRC**. The JRC's authority will continue to exist until the first to occur of (a) the Parties mutually agreeing to disband the JRC and (b) Vertex's election to terminate the JRC following the Research Term. Following any termination of the JRC, Vertex shall have the right to make all decisions that were allocated to the JRC and any communications designated to occur at the JRC shall occur between the Parties.

3.2. **Joint Steering Committee.**

3.2.1. **Formation**. Within [**] after the delivery to Vertex of the Profit Share Exercise Notice in accordance with Section 5.9.2, the Parties will establish a joint steering committee (the "**JSC**"). The JSC will be composed of [**] from each Party or such other equal number of representatives from each Party as the JSC may from time to time agree. Each Party's representatives on the JSC shall be of the seniority and

experience appropriate in light of the functions of the JSC. In addition, each Party may invite a reasonable number of additional representatives to participate in discussions and meetings of the JSC. Each Party's representatives on the JSC and all other individuals participating in discussions and meetings of the JSC on behalf of a Party will be subject to confidentiality and non-use obligations with respect to information disclosed at such meeting that are no less restrictive than the provisions of ARTICLE 10 except with respect to the duration of such obligations which will be commercially reasonable. [**] will designate the chairperson of the JSC. The chairperson of the JSC will be responsible for setting the agenda for meetings of the JSC with input from the other members, and for conducting the meetings of the JSC. The JSC will conduct its responsibilities hereunder in good faith and with reasonable care and diligence. The JSC will have no decision-making authority.

3.2.2. **Responsibilities**. The JSC will:

- (a) act as a forum to facilitate communication between the Parties with respect to the Development and Commercialization of Profit Share Products, including to:
 - (i) act as a forum to facilitate the sharing of the Development Plan for each Profit Share Product and any updates thereto;
 - (ii) as applicable, act as a forum to facilitate the sharing of the Commercialization Plan for each Profit Share Product and any updates thereto;
 - (iii) act as a forum to facilitate the sharing of the Program Expense Budget for each Profit Share Product and any updates thereto;
 - (iv) as applicable, act as a forum to facilitate the sharing of any updates regarding Other Company Activities in accordance with Section 2.9.3; and
- (b) facilitate the sharing of Research reports in accordance with Section 2.1.11 and of Development reports in accordance with Section 2.2.2.

3.2.3. **Meetings; Minutes**.

(a) The JSC will meet in person or by teleconference at least [**] on such dates and at such times and places as agreed to by the members of the JSC; *provided* that at least [**] shall be in person unless the Parties agree otherwise. Notwithstanding anything to the contrary in this Agreement, each Party will be responsible for its own expenses relating to attendance at, or participation in, JSC meetings.

- (b) The Alliance Managers will provide the members of the JSC with draft written minutes for approval from each meeting within [**] after each such meeting. The responsibility for preparing the minutes will alternate between the Alliance Managers on a meeting-by-meeting basis. If the minutes of any meeting of the JSC are not approved by the JSC (with each Party's representatives on the JSC collectively having one vote) within [**] after the meeting, the objecting Party will append a notice of objection with the specific details of the objection to the proposed minutes.
- 3.2.4. **Discontinuation of the JSC**. The JSC will continue to exist until the earlier to occur of (a) the Opt-Out Effective Date and (b) the date that Vertex exercises its right to terminate the JSC in accordance with Section 11.2.2(b)(i). Following any termination of the JSC, subject to the terms and conditions of this Agreement (including Section 11.2.2) any communications designated to occur at the JSC shall occur between the Parties.
- **IP Committee.** Within [**] after the Effective Date, the Parties will form an intellectual property committee 3.3. (the "IP Committee"), composed of an equal number of representatives from each Party having relevant expertise, to (a) coordinate the Prosecution and Maintenance and enforcement of Company Agreement Patents, Company System Patents, Licensed Patents and Joint Agreement Patents and (b) subject to confidentiality obligations to Third Parties undertaken by Company in good faith and not in an attempt to subvert this clause (b), discuss (i) any agreement that is material to the rights and licenses granted to Vertex under this Agreement and for which Company is contemplating entering into that would constitute a New Company Agreement if executed and (ii) any Patents or Know-How covered by any such contemplated New Company Agreement that would constitute New In-Licensed Technology if such contemplated New Company Agreement is executed. If any such Patents or Know-How specifically relate to a Company Gene Editing System or Company Delivery System that is the subject of Research Activities or that is included in a Licensed Agent contained in a Product with respect to which the Product Advancement Date has occurred, then Company shall use reasonable efforts to obtain from the applicable Third Party the right to discuss with Vertex under the foregoing clauses (b)(i) and (b)(ii) such Patents and Know-How, and any contemplated New Company Agreement with respect thereto. The IP Committee will meet in person or by means of telephone or video conference at least [**] during the Term or as the IP Committee may otherwise agree. Each Party may replace its representatives on the IP Committee at any time by providing notice in writing to the other Party. The IP Committee will have no decision-making authority but will act as a forum for discussion between the Parties with respect to matters relating to the ownership, prosecution and enforcement of Patents pursuant to this Agreement. In addition, each Party may invite a reasonable number of additional subject matter experts or relevant personnel of such Party to participate in discussions and meetings of the IP Committee. Each Party's representatives on the IP Committee and all other

individuals attending or participating in discussions and meetings of the IP Committee on behalf of a Party will be bound under written confidentiality and non-use obligations with respect to information disclosed at such meeting that are no less restrictive than the provisions of ARTICLE 10 except with respect to the duration of such obligations which will be commercially reasonable.

3.4. Other Committees. The Parties may, by mutual agreement, form such other committees or working groups as may be necessary or desirable to facilitate Agreement Activities and delegate certain responsibilities of the JRC or JSC to such committees or working groups.

3.5. **Alliance Managers**.

- 3.5.1. **Appointment**. Each Party will appoint a representative of such Party to act as its alliance manager under this Agreement (each, an "Alliance Manager"). Each Party will notify the other of its Alliance Manager within [**] after the Effective Date. Each Party may replace its Alliance Manager at any time upon notice to the other Party.
- 3.5.2. **Specific Responsibilities**. Unless the Parties otherwise agree in writing, the Alliance Managers will attend meetings of the JRC and JSC but may not be members of the JRC or JSC. The Alliance Managers will serve as the primary contact point between the Parties for the purpose of providing each Party with information regarding the other Parties' activities pursuant to this Agreement and will have the following responsibilities:
 - (a) schedule meetings of the JRC and JSC and circulate draft written minutes as provided in Section 3.1.3(b) and Section 3.2.3(b);
 - (b) facilitate the flow of information and otherwise promote communication, coordination and collaboration between the Parties;
 - (c) provide a single point of communication for seeking consensus both internally within the respective Party's organization and between the Parties regarding key strategy and planning issues; and
 - (d) perform such other functions as requested by the JRC or JSC.

ARTICLE 4. LICENSE GRANTS; EXCLUSIVITY

4.1. License Grants to Vertex.

4.1.1. Licenses.

(a) Company shall grant and hereby grants to Vertex and its Affiliates an exclusive, royalty-bearing license, including the right to grant Sublicenses through multiple tiers in accordance with Section 4.1.2,

- under Company's and its Affiliates' interests in the Licensed Technology, to Exploit the Licensed Agents and Products in the Field in the Territory.
- (b) Company shall grant and hereby grants to Vertex and its Affiliates a non-exclusive, royalty-free license, including the right to grant sublicenses through multiple tiers, under Company's and its Affiliates' interests in the Licensed Technology to make, have made, use, sell, offer for sale, import, export or otherwise exploit (including to research, develop, manufacture or commercialize) any diagnostic test or test system (including any in vitro diagnostic assay, laboratory developed test or in vitro clinical test) intended for use in connection with the Exploitation of a Product in the Field in the Territory.
- (c) Company shall grant and hereby grants to Vertex and its Affiliates a non-exclusive, royalty-free, fully paid-up, perpetual, irrevocable license, including the right to grant sublicenses through multiple tiers, under any (i) Overlapping Improvement within the Company Agreement Know-How and (ii) Company Agreement Patent claiming or covering any such Overlapping Improvement, in each case ((i) and (ii)), Controlled by Company or its Affiliates, to make, have made, use, sell, offer for sale, import, export or otherwise exploit (including to research, develop, manufacture or commercialize) any (A) Vertex Gene Editing System or Vertex Delivery System and (B) product that contains a Vertex Gene Editing System or Vertex Delivery System, in each case ((A) and (B)), in the Territory; *provided*, *however*, that the license set forth in this Section 4.1.1(c) will not be construed as a grant to Vertex or any of its Affiliates of any rights to any Company Gene Editing System or Company Delivery System to which any Overlapping Improvement is an improvement, modification or enhancement.
- 4.1.2. **Sublicensing**. Vertex and its Affiliates may grant sublicenses of any rights granted to Vertex and its Affiliates by Company under this Agreement through multiple tiers of sublicenses to one or more Third Parties. Each Sublicense must be consistent with the terms of this Agreement. Any Sublicense to a Sublicensee must be set forth in a written sublicense agreement that includes provisions that require such Sublicensee to comply with all the obligations, restrictions, terms and conditions of this Agreement that are applicable to the rights being granted to such Sublicensee and that enable Vertex to comply with its obligations under this Agreement. Notwithstanding any Sublicense, Vertex will remain responsible for each Sublicensee's compliance with the applicable terms of this Agreement as if such activities were conducted by Vertex and for any payments due hereunder with respect to any activities of any Sublicensee. Vertex will notify Company within [**]

following the grant of any Sublicense to a Sublicensee and within [**] following (a) the amendment of any such Sublicense in a manner that relates to the rights granted to Vertex under Section 4.1.1(a) or (b) the termination of any such Sublicense. Any such notice required by the preceding sentence following the grant of any such Sublicense or any amendment thereto will include a copy of such Sublicense or amendment, redacted except as necessary to confirm compliance with the terms of this Agreement. In the event that any Company In-License Agreement requires provision of a copy of any such Sublicense, Vertex agrees to provide such a copy (which may be redacted to the extent permitted by the Company In-License Agreement).

4.1.3. **Limitations**. Notwithstanding the licenses granted to Vertex pursuant to Section 4.1.1(a), Company will retain rights under the Licensed Technology to perform (a) Research Activities allocated to Company under the Research Plan during the Research Term, (b) if applicable, Additional Research Activities allocated to Company under an Additional Research Plan during the term of such Additional Research Plan and (c) if applicable, Other Company Activities allocated to Company under an Other Company Activities Plan during the term of such Other Company Activities Plan.

4.2. <u>License Grants to Company</u>.

4.2.1. Licenses.

Subject to the terms and conditions of this Agreement, Vertex shall grant and hereby grants to (a) Company and its Affiliates a non-exclusive license in the Territory, with no right to grant sublicenses except to permitted Subcontractors, under (i) any Know-How Controlled by Vertex or its Affiliates and actually provided to Company hereunder, and (ii) any Patents Controlled by Vertex or its Affiliates necessary or reasonably useful to perform (A) the Research Activities allocated to Company under the Research Plan during the Research Term, (B) if applicable, Additional Research Activities allocated to Company under an Additional Research Plan during the term of such Additional Research Plan and (C) if applicable, Other Company Activities allocated to Company under an Other Company Activities Plan during the term of such Other Company Activities Plan; in each case ((i) and (ii)), solely to perform (1) any Research Activities allocated to Company under the Research Plan during the Research Term, (2) if applicable, any Additional Research Activities allocated to Company under an Additional Research Plan during the term of such Additional Research Plan and (3) if applicable, any Other Company Activities allocated to Company under an Other Company Activities Plan during the term of such Other Company Activities Plan.

Vertex shall grant and hereby grants to Company and its Affiliates a non-exclusive, royalty-(b) free, fully paid-up, perpetual, irrevocable license, including the right to grant sublicenses through multiple tiers, under any (i) Overlapping Improvement within the Vertex Agreement Know-How and (ii) Vertex Agreement Patent claiming or covering any such Overlapping Improvement, in each case ((i) and (ii)), Controlled by Vertex or its Affiliates, to make, have made, use, sell, offer for sale, import, export or otherwise exploit (including to research, develop, manufacture or commercialize) any (A) Company Gene Editing System or Company Delivery System and (B) product that contains a Company Gene Editing System or Company Delivery System, in each case ((A) and (B)), in the Territory; provided that the license granted under this Section 4.2.1(b) excludes rights to exploit any Company Gene Editing System, Company Delivery System, or product that contains a Company Gene Editing System or Company Delivery System, in each case, for the treatment, prevention or diagnosis of [**]: provided, however, that the license set forth in this Section 4.2.1(b) will not be construed as a grant to Company or any of its Affiliates of any rights to any Vertex Gene Editing System or Vertex Delivery System to which any Overlapping Improvement is an improvement, modification or enhancement.

4.3. <u>Technology Transfer</u>.

4.3.1. **General**.

- (a) From time to time, Company will promptly transfer to Vertex all Licensed Know-How that is reasonably necessary for Vertex to conduct the activities allocated to it in the Research Plan, by providing copies or samples of relevant documentation (whether in paper or electronic form, including standard operating procedures and technical specifications), materials and other embodiments of such Licensed Know-How, and by making available its, or its applicable Affiliate's or Third Party's qualified technical personnel on a reasonable basis to consult with Vertex with respect to such Licensed Know-How.
- (b) At Vertex's request from time to time any time after the occurrence of the Product Advancement Date with respect to any Product, Company will transfer to Vertex all Licensed Know-How related to such Product or any Licensed Agent contained in such Product, in each case, that (i) has not been previously transferred to Vertex under this Agreement, and (ii) either (A) was used or relied upon by Company or its Affiliates in conducting the Research Plan or (B) is otherwise reasonably necessary for the Exploitation of such Licensed Agent or Product, by providing copies or samples of

relevant documentation (whether in paper or electronic form, including standard operating procedures and technical specifications), materials and other embodiments of such Licensed Know-How, and by making available its, or its applicable Affiliate's or Third Party's qualified technical personnel on a reasonable basis to consult with Vertex with respect to such Licensed Know-How.

- 4.3.2. **Assistance by Company Personnel**. Without limitation to the foregoing, to assist with the transfer of Licensed Know-How under this Section 4.3 and Vertex's exploitation thereof in accordance with the terms of this Agreement, Company will make its personnel reasonably available to Vertex during normal business hours to transfer such Licensed Know-How to Vertex and respond to Vertex's inquiries with respect thereto.
- 4.3.3. **Company Expenses**. In connection with Company's activities under (a) Section 4.3.1(b) or (b) Section 4.3.2 to the extent applicable to activities under Section 4.3.1(b), Company shall submit an invoice to Vertex setting forth Company's reasonable Expenses associated with such activities and Vertex will pay the undisputed portion of any such invoice within [**] after receipt thereof.
- 4.4. **No Implied Licenses**. Except as expressly provided in this Agreement, neither Party will be deemed by estoppel or implication to have granted the other Party any licenses or other right with respect to any intellectual property.
- 4.5. **Exclusivity Covenants.** Subject to Sections 4.6, 4.7 and 4.8, Company, on behalf of itself and its Affiliates, covenants to Vertex that during the Term, except in the performance of its obligations or exercise of its rights under this Agreement, neither Company nor any of its Affiliates will work independently or for or with, or grant any license or other rights to, any Third Party with respect to the [**].
- 4.6. Change of Control. If there is a Change of Control where Company is the acquired entity, the obligations of Section 4.5 will not apply to any product that is controlled by an Acquirer; provided that (a) Company (and its Affiliates existing immediately prior to the effective date of such Change of Control) and the Acquirer establish and enforce internal processes, policies, procedures and systems to segregate information relating to any [**] ("Relevant Confidential Information"), (b) the Acquirer does not use or practice, directly or indirectly, any Patents or Know-How of Company or any Relevant Confidential Information of Company (or its Affiliates existing immediately prior to the effective date of such Change of Control) in the [**] (including any Patents, Know-How or Confidential Information licensed or acquired from Vertex or its Affiliates under this Agreement), and (c) no personnel who were employees or consultants of Company (or its Affiliates existing immediately prior to the effective date of such Change of Control) at any time prior to or after the Change of Control conducts any activities with respect to such product if [**].

- 4.7. Acquisition of Distracting Product. Notwithstanding Section 4.5, if Company or any of its Affiliates acquires rights to research, develop, manufacture or commercialize a product for use in the [**] as the result of a merger, acquisition or combination with or of a Third Party other than a Change of Control where Company is the acquired entity (each, an "Acquisition Transaction") and, on the date of the closing of such Acquisition Transaction, such product is being researched, developed, manufactured or commercialized and such activities would, but for the provisions of this Section 4.7, constitute a breach of Section 4.5 (such product, a "Distracting Product"), then Company or such Affiliate will, within [**] after the closing of such Acquisition Transaction notify Vertex in writing of such acquisition and either:
 - (a) request that such Distracting Product be included in this Agreement on terms to be negotiated, in which case, the Parties will discuss the matter in good faith for a period of no less than [**] (or such longer period as may be agreed by the Parties) and, if unable to reach agreement on the terms on which such Distracting Product would be included hereunder within such period, Company will elect to take the action specified in either clause (b) or (c) below; *provided* that the time periods specified in such clauses will be tolled for so long as the Parties are engaged in discussion under this clause (a);
 - (b) notify Vertex in writing that Company or its Affiliate will Divest such Distracting Product, in which case, within [**] after the closing of the Acquisition Transaction, Company or its Affiliate will Divest such Distracting Product; or
 - (c) notify Vertex in writing that it is ceasing all such research, development, manufacturing and commercialization activities with respect to the Distracting Product, in which case, within [**] after Vertex's receipt of such notice, Company and its Affiliates will cease all such activities; provided, however, that with respect to any Clinical Trial with respect to a Distracting Product that is ongoing as of the date that Company acquires rights to such Distracting Product, Company shall have the right to continue or complete such Clinical Trial solely to the extent reasonably necessary to comply with its ethical obligations; provided that Company shall not (i) expand any such Clinical Trial (for clarity, even if the protocol for such Clinical Trial permits expansion) or (ii) file for marketing approval of such Distracting Product or otherwise research, develop, manufacture or commercialize such Distracting Product.

During the discussion period under clause (a), prior to the time of divestiture pursuant to clause (b) or prior to the termination of activities pursuant to clause (c), as applicable, Company and its Affiliates will use Commercially Reasonable Efforts to segregate all discovery, research, development, manufacturing or commercialization activities relating to the Distracting Product from Research, Development, Manufacture and Commercialization with respect to Licensed

Agents or Products under this Agreement, including using Commercially Reasonable Efforts to ensure that (i) no personnel involved in performing discovery, research, development, manufacturing or commercialization activities with respect to such Distracting Product have access to non-public plans or information relating to the Research, Development, Manufacture or Commercialization of Licensed Agents or Products under this Agreement (except that management personnel may review and evaluate plans and information regarding the Research, Development and Commercialization of Products under this Agreement in connection with portfolio decision-making) and (ii) no personnel involved in performing Research, Development, Manufacture or Commercialization activities with respect to Licensed Agents or Products under this Agreement have access to non-public plans or information relating to the discovery, research, development, manufacture or commercialization of such Distracting Product (except that management personnel may review and evaluate plans and information regarding the discovery, research, development, manufacture and commercialization of such Distracting Product in connection with portfolio decision-making).

4.8. [**] Agreement. The Parties acknowledge that Company is a party to an [**] Agreement, dated [**], with [**] (such agreement, as in effect as of the Effective Date, the "[**] Agreement"), pursuant to which [**] for purposes of this Agreement. The grant of rights and performance of obligations under the [**] Agreement will not be a breach of Section 4.5; provided that Company and its Affiliates (i) do not perform any research, development, manufacture or commercialization activities related to any [**] and (ii) [**].

ARTICLE 5. FINANCIAL PROVISIONS

- 5.1. <u>Up-Front Fee</u>. Within five Business Days following the Effective Date, Vertex will pay Company a one-time non-refundable, non-creditable up-front fee of \$25,000,000.
- 5.2. Equity Investment. On the Effective Date, the Parties will enter into a stock purchase agreement (the "SPA") pursuant to which Company will sell to Vertex in one transaction, and Vertex will purchase from Company, \$35,000,000 worth of shares of common stock of Company, as more specifically set forth in such SPA; provided that if such purchase would result in ownership by Vertex of more than 4.9% of Company's common stock, then such amount will be reduced such that Vertex will own 4.9% of Company's common stock.

5.3. Success Payments.

5.3.1. Success Payments. Subject to this Section 5.3.1, in the event that the Development Candidate Criteria are achieved for any Type 1 Product or Type 2 Product, Vertex will, in accordance with the procedure set forth in Section 5.3.2, pay Company a non-refundable, non-creditable success payment of (a) \$[**] for achievement of the Development Candidate Criteria by a Type 1 Product and (b) \$22,000,000 for achievement of the Development Candidate Criteria by a Type 2 Product. Such success

payments will be payable up to three times, regardless of whether the first three Products to achieve the Development Candidate Criteria are Type 1 Products or Type 2 Products; *provided* that if any such three achievements are by a Type 1 Product and the Development Candidate Criteria are later achieved by a Type 2 Product, then Vertex will pay Company the difference between the Type 2 Product success payment and the Type 1 Product success payment (*i.e.*, \$[**]). Notwithstanding anything to the contrary herein, (i) the aggregate amount of all success payments payable pursuant to this Section 5.3.1 shall in no event exceed \$66,000,000, for clarity, regardless of the [**] that achieve the Development Candidate Criteria and (ii) each success payment is payable only once for any Product containing a particular Licensed Agent, regardless of the [**] achieve the Development Candidate Criteria.

5.3.2. **Notice; Payment**. Each Party will provide the other Party with written notice upon the achievement of the Development Candidate Criteria by such Party or any of its Affiliates (or, in the case of Vertex, its Sublicensees) with respect to any Product within [**] after such achievement. Following delivery of such written notice, Company will promptly invoice Vertex for any applicable success payment owed pursuant to Section 5.3.1 and Vertex will make the appropriate success payment within [**] after receipt of such invoice.

5.4. <u>Milestone Payments</u>.

5.4.1. **Research, Development & Regulatory Milestones**. Vertex will pay Company the non-refundable, non-creditable milestone payments set forth in this Section 5.4.1, subject to Section 5.4.3 and in accordance with the procedure set forth in Section 5.4.4, upon the first achievement of the relevant milestone event by Vertex or any of its Affiliates or Sublicensees.

Milestone Number	Milestone Event	Milestone Payment for a Type 1 Product	Milestone Payment for a Type 2 Product (subject to Section 5.4.3)
1	[**]	[**]	[**]
2	[**]	[**]	[**]
3	[**]	[**]	[**]
4	[**]	[**]	[**]

5.4.2. **Commercial Milestones**. Vertex will pay Company the non-refundable, non-creditable milestone payments set forth in this Section 5.4.2, subject to Section 5.4.3 and in accordance with the procedure set forth in Section 5.4.4, upon the first achievement of the relevant milestone event by Vertex or its Affiliates or any Sublicensees.

Milestone Number	Milestone Event	Milestone Payment for a Type 1 Product	Milestone Payment for a Type 2 Product (subject to Section 5.4.3)
5	Annual Net Sales of a Royalty Product exceed \$[**]	[**]	[**]
6	Annual Net Sales of a Royalty Product exceed \$[**]	[**]	[**]
7	Annual Net Sales of a Royalty Product exceed \$[**]	[**]	[**]

- 5.4.3. **Payment for Multiple Royalty Products**. Each milestone payment set forth in Section 5.4.1 or Section 5.4.2, is payable only once, regardless of the number of Royalty Products that achieve the relevant milestone event or the number of times a Royalty Product achieves the relevant milestone event; *provided* that if such first achievement of any such milestone event is by a Type 1 Product and such milestone event is subsequently achieved by a Type 2 Product, then Vertex shall pay Company the difference between the applicable Type 2 Product milestone payment and the applicable Type 1 Product milestone payment in accordance with the procedure set forth in Section 5.4.4. Notwithstanding anything to the contrary herein, (a) the aggregate amount of milestone payments payable pursuant to Section 5.4.1 (after any adjustment required pursuant to this Section 5.4.3) shall in no event exceed \$[**] and (b) the aggregate amount of milestone payments payable pursuant to Section 5.4.2 (after any adjustment required pursuant to this Section 5.4.3) shall in no event exceed \$[**], in each case ((a) and (b)), for clarity, regardless of the number of Products that achieve any particular milestone event.
- 5.4.4. **Notice; Payment; Skipped Milestones**. Vertex will provide Company with written notice upon the achievement of each of the milestone events set forth in Section 5.4.1 and Section 5.4.2, such written notice to be provided (a) with respect to any milestone event under Section 5.4.1, within [**] after such achievement and (b) with respect to any milestone event under Section 5.4.2, on or prior to the date of delivery of the Royalty Report under Section 5.5.7 for the [**] in which such milestone event is first achieved. Following receipt of such written notice, Company will promptly invoice Vertex for the applicable milestone payment and Vertex will make the appropriate milestone payment within [**] after receipt of such invoice. Each milestone payment corresponding with the milestones numbered [**] as set forth in Section 5.4.1 are intended to be successive; if a Royalty Product is not required to undergo the event associated with any such milestone event, such skipped milestone will be deemed to have

been achieved upon the achievement by such Royalty Product of the next successive milestone event. Payment for any such skipped milestone that is owed in accordance with the provisions of the foregoing sentence with respect to a given Royalty Product will be due concurrently with the payment for the achievement of the next successive milestone event by such Royalty Product, it being agreed that if a Royalty Product is not required to undergo the milestone numbered [**] the corresponding payment will be made upon the first to occur of the milestones numbered [**]. The commercial milestone payments in Section 5.4.2 are additive, such that if more than one milestone event specified in Section 5.4.2 above is achieved in the same Calendar Year, then each corresponding commercial milestone payment for such events will be payable.

5.5. **Royalties**.

5.5.1. **Royalty Rates**. Subject to Sections 5.5.2, 5.5.3, 5.5.4, 5.5.5 and 5.5.6, on a Royalty Product-by-Royalty Product basis, Vertex will pay Company royalties based on the aggregate Net Sales of each Royalty Product sold by Vertex, its Affiliates or Sublicensees in the Field in the Territory during a Calendar Year at the rates set forth in the table below. The obligation to pay royalties will be imposed only once with respect to the same unit of a Royalty Product.

Annual Net Sales (in Dollars) for such Royalty Product in the Territory	Royalty Rates as a Percentage (%) of Net Sales for a Type 1 Product	Royalty Rates as a Percentage (%) of Net Sales for a Type 2 Product
Portion of Annual Net Sales up to and including \$[**]	[**]%	[**]%
Portion of Annual Net Sales that exceeds \$[**] up to and including \$[**]	[**]%	[**]%
Portion of Annual Net Sales that exceeds \$[**]	[**]%	[**]%

8.5.2. **Royalty Term**. Vertex will pay royalties to Company under this Section 5.5 on a Royalty Product-by-Royalty Product and a country-by-country basis during the Royalty Term for the applicable Product in the applicable country. Upon the expiration of the Royalty Term for a given Royalty Product in a given country, the license granted to Vertex under Section 4.1.1(a) will become fully-paid, perpetual and irrevocable with respect to such Royalty Product in such country.

- 5.5.3. **Reduction for Lack of Patent Coverage and Regulatory Exclusivity**. If during any period within the applicable Royalty Term for a Royalty Product in a given country, (a) no Valid Claim of a Licensed Patent exists that Covers such Royalty Product in such country, and (b) all applicable regulatory exclusivity periods, including data exclusivity periods, have expired in such country with respect to such Royalty Product, Net Sales of such Royalty Product in such country will be reduced by [**]% for purposes of calculating the royalty owed under Section 5.5.1 for the remainder of the Royalty Term.
- 8.5.4. **Reduction for Competition**. If (a) during any [**] within the applicable Royalty Term for a Royalty Product in a given country, (i) an Equivalent Product with respect to such Royalty Product is sold during such [**] in such country, and (ii) the Net Sales of such Royalty Product are less than [**]% of the Net Sales of such Royalty Product in such country in the Calendar Year preceding the marketing or sale of the first Equivalent Product, then (b) the Net Sales of such Royalty Product will be reduced by [**]% for purposes of calculating the royalty owed under Section 5.5.1 for the remainder of the Royalty Term.
- 5.5.5. **Third Party Licenses**. Vertex may deduct from the royalties payable to Company for a Royalty Product under this Section 5.5 [**]% of any Selected Third Party Intellectual Property Costs with respect to such Royalty Product paid by Vertex, its Affiliates or Sublicensees; *provided, however*, [**]. For clarity, this Section 5.5.5 shall apply to any Selected Third Party Intellectual Property Costs, regardless of when such Selected Third Party Intellectual Property Costs are paid by Vertex, its Affiliates or Sublicensees, including to Selected Third Party Intellectual Property Costs paid prior to the Royalty Term. Subject to Section 5.5.6, Vertex shall have the right to apply any uncredited reduction in royalties under this Section 5.5.5 to any subsequent [**] until such reduction is fully realized.
- 5.5.6. **Aggregate Limitation on Deductions**. Notwithstanding Sections 5.5.3, 5.5.4, and 5.5.5, in no event will the combined effect of all reductions to the royalties payable to Company under Sections 5.5.3, 5.5.4 and 5.5.5 reduce the royalty payable by Vertex to Company under this Section 5.5 for any Royalty Product in any country during a [**] to less than [**]% of the amount that would otherwise be due under Section 5.5.1, but for such deductions.
- 5.5.7. **Royalty Reports**. Following the first sale of a Royalty Product giving rise to Net Sales and continuing for the remainder of the Royalty Term for such Product, (a) within [**] after the end of each [**], Vertex will provide a good faith estimate of Net Sales for all Royalty Products and (b) within [**] after the end of each [**], Vertex will deliver a report (each a "**Royalty Report**") to Company specifying on a Royalty

Product-by-Royalty Product and country-by-country basis: (i) Net Sales in the relevant [**]; (ii) to the extent such Net Sales include sales not denoted in U.S. Dollars, a summary of the then-current exchange rate methodology(ies) used for the calculation of Net Sales in accordance with Section 5.10.2, and (iii) royalties payable on such Net Sales. All royalty payments due under Section 5.5 for each [**] will be due and payable within [**] after the end of each [**].

5.6. <u>Company Agreements</u>. Except as otherwise expressly provided in this Agreement, as between the Parties, Company shall be responsible for all payment obligations arising under any agreement to which Company or its Affiliate is a party.

5.7. Company In-License Agreements.

5.7.1. **Existing In-License Agreement**. Certain Patents Controlled by Company or its Affiliates as of the Effective Date and included in the Licensed Technology are in-licensed by Company under an agreement with a Third Party. Such agreement is listed on <u>Schedule 5.7.1-1</u> (the "**Existing In-License Agreement**"). Vertex acknowledges receipt of a copy of the Existing In-License Agreement, and agrees to be bound by the terms thereof that are identified in <u>Schedule 5.7.1-2</u>, to the extent such terms are applicable to the sublicense granted herein by Company to Vertex under the Existing In-License Agreement.

5.7.2. New Company Agreements.

(a) Company may (but will not be required to) enter into any agreement with a Third Party (the "Grantor") on or after the Effective Date pursuant to which it licenses or acquires rights to Patents or Know-How that would, if solely owned by Company without any encumbrance or restriction on licensing, constitute Licensed Technology (such agreements, the "New Company Agreements", and such Patents or Know-How, the "New In-Licensed **Technology**"). In such event Company will use good faith efforts to ensure that the New In-Licensed Technology covered by any such New Company Agreement will be licensable or sublicensable to Vertex to the same extent that Licensed Technology is licensed to Vertex hereunder (including the right to grant sublicenses through multiple tiers) and will not impose any material restrictions or obligations on Vertex as a licensee or sublicensee or disadvantage Vertex as compared to any other potential licensee or sublicense under such New Company Agreement. If, after using such good faith efforts, Company is not able to ensure any of the foregoing, then Company will not enter into an exclusive license with respect to such New In-Licensed Technology for purposes of discovery, research, development, manufacture, commercialization or other exploitation of any product for use in the [**].

Promptly following execution of a New Company Agreement, Company shall provide to (b) Vertex a copy of such New Company Agreement (which may be redacted to exclude provisions thereof that would not be applicable to Vertex as a licensee or sublicensee) with a summary of the terms of such agreement that would be applicable to Vertex as a licensee or sublicensee (as the case may be) thereunder (a "Licensee"), including any financial obligations that would be owed to the applicable Grantor, as a result of the Exploitation of any Product or Licensed Agent by Vertex or any of its Affiliates or Sublicensees if the New In-Licensed Technology covered by such New Company Agreement were to become Licensed Technology under this Agreement. Following written notice by Vertex that it desires to (i) have the New In-Licensed Technology covered by a particular New Company Agreement included in the Licensed Technology and (ii) become subject to the terms of such New Company Agreement that are applicable to a Licensee thereunder as identified in the summary of terms provided to Vertex hereunder or as otherwise agreed by the Parties (each of such notices, a "New Company Agreement Election Notice"), such New In-Licensed Technology shall automatically be deemed included in the Licensed Technology.

5.7.3. Payment Obligations Under Company In-License Agreements.

- (a) Payment Obligations Related to Royalty Products.
 - (i) Existing In-License Agreement.
 - (A) General. To the extent that any amount becomes payable under the Existing In-License Agreement as a result of the Exploitation of any Royalty Product or Licensed Agent contained in a Royalty Product by Vertex or any of its Affiliates or Sublicensees, Company will be responsible for such amount, except that Vertex shall be responsible for amounts that become payable under Sections 4.2, 4.3 and 4.4 of the Existing In-License Agreement, following application of Section 4.5 of the Existing In-License Agreement ("Vertex Amounts"). Vertex shall pay the Vertex Amounts in accordance with Sections 5.7.3(a)(i)(B) through 5.7.3(a)(i)(E), as applicable. Vertex Amounts paid by Vertex or its Affiliates or Sublicensees shall be deemed to be Selected Third Party Intellectual Property Costs paid by Vertex pursuant to Section 5.5.5.

- (B) **Royalty Payments.** For Vertex Amounts that become payable under Section 4.4 of the Existing In-License Agreement, following application of Section 4.5 thereof, Vertex shall, notwithstanding Section 5.5.7: (1) deliver a Royalty Report to Company within [**] after the end of each [**] and (2) pay to Company any royalty payments due under Section 4.4 of the Existing In-License Agreement, following application of Section 4.5 thereof, within [**] after delivering such Royalty Report.
- (C) **Development Milestone Payments.** For Vertex Amounts that become payable under Section 4.2 of the Existing In-License Agreement, Vertex shall, notwithstanding Section 5.4.4: (1) provide Company with written notice within [**] after achievement of the applicable milestone event set forth in Section 4.2 of the Existing In-License Agreement and (2) pay to Company the corresponding milestone payment due under Section 4.2 of the Existing In-License Agreement within [**] after delivering such notice.
- (D) Sales Milestone Payments. For Vertex Amounts that become payable under Section 4.3 of the Existing In-License Agreement, (1) Vertex shall provide Company with the Royalty Report in accordance with Section 5.7.3(a)(i)(B); (2) Company shall promptly determine if any milestone event set forth in Section 4.3 of the Existing In-License Agreement has been achieved and, if so, invoice Vertex for the applicable amount of the corresponding milestone payment (or portion thereof), in accordance with the apportionment mechanism as set forth in Section 5.7.3(a)(i)(E); and (3) Vertex shall pay the undisputed amounts of any such invoice within [**] after receipt thereof.
- (E) Apportionment of Sales Milestone Payments. With respect to any payments owed by Vertex under Section 5.7.3(a)(i)(D), the amount owed by Vertex with respect to the achievement of any particular sales milestone event in a given Calendar Year shall be determined by the formula (X/Y)*Z, where X is "Net Sales" (as defined in the Existing In-License Agreement, such "Net Sales", "Existing

In-License Agreement Net Sales") of all Products under this Agreement in a given Calendar Year that are also "Products" under the Existing In-License Agreement; Y is the sum of (1) X and (2) Existing In-License Agreement Net Sales of all other "Products" under the Existing In-License Agreement in a given Calendar Year that are, in accordance with the terms of the Existing In-License Agreement (including Section 4.3(d) thereof), aggregated together with Existing In-License Agreement Net Sales of Products under this Agreement for purposes of determining whether the applicable sales milestone event has been achieved; and Z is the milestone payment corresponding to such sales milestone event. For example, [**].

(ii) New Company Agreements. To the extent that any amount (including royalties or other payment obligations) becomes payable under a New Company Agreement with respect to which Vertex has provided a New Company Agreement Election Notice as a result of the Exploitation of any Royalty Product or Licensed Agent contained in a Royalty Product by Vertex or any of its Affiliates or Sublicensees (after application of all available reductions to and deductions from such amount under the applicable New Company Agreement (but, for the avoidance of doubt, excluding any payment obligations of Company or its Affiliates with respect to licensing or sublicensing income)) ("New Company Agreement Amounts"), Vertex will be responsible for such New Company Agreement Amounts. With respect any New Company Agreement Amounts that become payable based on net sales of Products, following receipt by Company from Vertex of a Royalty Report with respect to any [**], Company shall promptly provide Vertex with a reasonably detailed invoice for any such New Company Agreement Amounts, and Vertex (itself or through its Affiliates or Sublicensee) shall pay the undisputed portion of any such invoice within [**] of receipt thereof. With respect to any other New Company Agreement Amounts that become payable, Company shall promptly provide Vertex with a reasonably detailed invoice for any such New Company Agreement Amounts after such New Company Agreement Amounts become payable, and Vertex (itself or through its Affiliates or Sublicensee) shall pay the undisputed portion of any such invoice within [**] of receipt thereof. Any New Company Agreement Amounts paid by Vertex or its Affiliates or Sublicensees shall be deemed to

be Selected Third Party Intellectual Property Costs paid by Vertex pursuant to Section 5.5.5.

- (b) Payment Obligations Related to Profit Share Products To the extent that any amount (including royalties or other payment obligations) (i) becomes payable under a Company In-License Agreement as a result of the Exploitation of any Profit Share Product or Licensed Agent contained in a Profit Share Product (A) by Vertex or any of its Affiliates or Sublicensees or (B) by Company or any of its Affiliates in the performance of Other Company Activities; and (ii) arises on or after the Profit Share Effective Date, such amount (after application of all available reductions to and deductions from such amount under the applicable Company In-License Agreement (but, for the avoidance of doubt, excluding any payment obligation of Company or its Affiliates with respect to licensing or sublicensing income)) shall be paid by Company to the applicable Grantor and deemed Other Out-of-Pocket Expenses hereunder.
- (c) **Abandonment of Payment Obligations**. Notwithstanding the foregoing, Vertex may, in its sole discretion, notify Company in writing that it elects to abandon its payment obligations under this Section 5.7.3 with respect to any Company In-License Agreement, whereupon such Company In-License Agreement shall be deemed not to be a Company In-License Agreement and any intellectual property rights included in the Licensed Technology pursuant to such Company In-License Agreement shall be deemed not to be included in the Licensed Technology as of the date of such written notice. For clarity, Vertex acknowledges and agrees that it will not be granted any rights hereunder to practice any Patents or Know-How covered by any such abandoned Company In-License Agreement after such written notice.

5.8. **Research Funding**.

Research Costs. During the Research Term, Vertex will reimburse Company for its FTE Costs and Out-of-Pocket Costs actually incurred by Company or its Affiliates for Research Activities performed in accordance with Research Plan (including the Research Budget), except to the extent any such FTE Costs and Out-of-Pocket Costs are allocable to a Profit Share Product pursuant to Section 5.9; provided that (a) Vertex shall not reimburse Company for any FTE Costs or Out-of-Pocket Costs incurred during any [**] in the conduct of Research Activities in excess of [**]% of the relevant Research Budget for such [**] and (b) Company shall be solely responsible for all such excess expenses above [**]% of the Research Budget incurred during such [**], unless otherwise agreed in writing by Vertex. Vertex will be responsible for its costs and expenses

incurred in the performance of Research Activities, except to the extent such costs and expenses constitute Vertex Research Expenses.

- 5.8.2. Additional Research Costs. Vertex will reimburse Company for its FTE Costs and Out-of-Pocket Costs actually incurred by Company or its Affiliates for Additional Research Activities performed in accordance with Additional Research Plan and Additional Research Budget, except to the extent any such FTE Costs and Out-of-Pocket Costs are allocable to a Profit Share Product pursuant to Section 5.9; provided that (a) Vertex shall not reimburse Company for any FTE Costs or Out-of-Pocket Costs incurred during any [**] in the conduct of Additional Research Activities in excess of [**]% of the relevant Additional Research Budget for such [**] and (b) Company shall be solely responsible for all such excess expenses above [**]% of the Additional Research Budget incurred during such [**], unless otherwise agreed in writing by Vertex.
- Payments. Any payments to be made to Company by Vertex pursuant to this Section 5.8 shall be made [**] in arrears pursuant to invoices submitted by Company to Vertex within [**] following the end of the applicable [**] for which such costs have been incurred; *provided* that Company shall provide a good faith written estimate of any costs for which reimbursement is due under this Section 5.8 within [**] after each [**]. Each such invoice will be accompanied by reasonable supporting documentation evidencing the expenses incurred for Research Activities or Additional Research Activities (such Research Activities or Additional Research Plan (including the Research Budget) or Additional Research Plan and Additional Research Budget) during such [**]. Undisputed payments shall be due within [**] after Vertex receives such an invoice from Company.

5.9. **Profit Share**.

- 5.9.1. **Information Sharing** On or about the date that is [**] prior to Vertex's reasonable estimate of the date of Initiation of the first Phase 1 Clinical Trial for the first Product, Vertex will provide Company with the Opt-In Information Package (the delivery date of the Opt-In Information Package, the "**Opt-In Information Package Delivery Date**"). The Opt-In Information Package will be deemed Vertex's Confidential Information. At Company's reasonable request, Vertex will meet with Company following delivery of the Opt-In Information Package to discuss the contents of the Opt-In Information Package with Company and answer any questions with respect thereto.
- 5.9.2. **Profit Share Option Exercise**. Subject to Section 11.2.2, Company will have the one-time right to convert all Products (unless Company has previously exercised its Opt-Out right pursuant to Section 5.9.4(a)) to

Profit Share Products (such right, the "Profit Share Option") by written notice to Vertex (such notice, the "Profit Share Exercise Notice") at any time beginning on the Effective Date and continuing until the day prior to Initiation of the first Phase 1 Clinical Trial for the first Product, which written notice shall specify the Profit Share Split elected by Company. Company's exercise of the Profit Share Option shall become effective as of [**] in which the Profit Share Exercise Notice is delivered to Vertex (such date, the "Profit Share Effective Date"). If Company fails to timely exercise the Profit Share Option in accordance with this Section 5.9.2, then the Profit Share Option shall expire and be of no further force or effect with respect to any and all Products. For clarity, except to the extent set forth in an Other Company Activities Plan in accordance with Section 2.9, Company will have no right or obligation to perform any Development, Manufacturing or Commercialization activities with respect to any Profit Share Product and Vertex will solely control all such activities.

5.9.3. **Profit Share Option Fee**. Company will pay Vertex the following fee, as applicable, within [**] following the Profit Share Effective Date: (a) if Company elects 60% Vertex and 40% Company as the Profit Share Split, then (i) \$70,000,000 if the most advanced Product as of the Profit Share Effective Date is a Type 1 Product or (ii) \$[**] if the most advanced Product as of the Profit Share Effective Date is a Type 2 Product; and (b) if Company elects [**]% Vertex and [**]% Company as the Profit Share Split, then (i) \$[**] if the most advanced Product as of the Profit Share Effective Date is a Type 1 Product or (ii) \$25,000,000 if the most advanced Product as of the Profit Share Effective Date is a Type 2 Product. If Company does not pay the applicable fee within such [**] period, then Vertex may deliver written notice of such payment default to Company. Notwithstanding anything to the contrary in this Agreement, if Company does not cure such payment default within [**] following the date of such notice, then Vertex shall have the right, upon further written notice to Company and without limitation to any other right or remedy available to Vertex, to deem the Opt-Out to be exercised, and the Opt-Out Effective Date shall be deemed to be the date of such further written notice.

5.9.4. Profit Share Opt-Out; Profit Share Split Step-Down.

(a) **Profit Share Opt-Out**. Company will have the right to convert all Profit Share Products to Royalty Products (such right, the "**Opt-Out**") by written notice to Vertex (such notice, the "**Opt-Out Notice**") at any time after the Profit Share Effective Date. If Company provides the Opt-Out Notice, the Opt-Out shall become effective [**] following the delivery of the Opt-Out Notice (the effective date of the Opt-Out, as applicable, the "**Opt-Out Effective Date**").

(b) **Profit Share Split Step-Down**. If Company elects 60% Vertex and 40% Company as the Profit Share Split in the Profit Share Exercise Notice, then Company will have the right to change the Profit Share Split to [**]% Vertex and [**]% Company (such right, the "**Profit Share Split Step-Down**") by written notice to Vertex (such notice, the "**Profit Share Split Step-Down Notice**") at any time after the Profit Share Effective Date but before the delivery of the Opt-Out Notice. If Company provides the Profit Share Split Step-Down Notice, the Profit Share Split Step-Down shall become effective [**] following the delivery of the Profit Share Split Step-Down Notice (the effective date of the Profit Share Split Step-Down, as applicable, the "**Profit Share Split Step-Down Effective Date**"). For clarity, if Company provides the Profit Share Split Step-Down Notice, then (a) Company shall not be entitled to any refund for amounts paid prior to the Profit Share Split Step-Down Effective Date and (b) the 60% Vertex and 40% Company Profit Share Split shall continue to apply until the occurrence of the Profit Share Split Step-Down Effective Date.

5.9.5. Plans and Budget; Estimated Build-Out Expenses. With respect to each Profit Share Product:

- (a) within [**] after the Profit Share Effective Date (or on a date reasonably agreed by both Parties with respect to Profit Share Products that do not exist as of the Profit Share Effective Date), subject to Section 11.2.2(b)(ii), Vertex will provide the JSC a Development Plan and a Commercialization Plan with respect to such Profit Share Product;
- (b) beginning [**] after the Profit Share Effective Date and on or about [**] of each [**], Vertex will provide the JSC (i) a non-binding, good faith estimate of Program Expenses to be incurred by Vertex or its Affiliates for each Profit Share Product during the subsequent [**] (such estimate the "**Program Expense Budget**" for such Profit Share Product) and (ii) as applicable, and subject to Section 11.2.2(b)(ii), written update(s) to the Development Plan and the Commercialization Plan;
- (c) on a [**] basis after the initial Program Expense Budget submission to the JSC, Vertex shall provide an update to the Program Expense Budget within [**] of the close of each [**], which updates shall include any material changes to the estimated Build-Out Expenses provided to Company under Section 5.9.5(d); and
- (d) Vertex will provide to Company, for any Build-Out Expenses (i) not already included in a Program Expense Budget and (ii) to be incurred by Vertex or its Affiliates (A) for a new Manufacturing

facility or (B) at a Manufacturing facility not previously used to Manufacture such Profit Share Product, a non-binding, good faith estimate of such Build-Out Expenses.

- 5.9.6. **Allocation**. With respect to each Profit Share Product, each Party will be entitled to its applicable percentage of the Net Profits set forth in the elected Profit Share Split (if applicable, as changed in accordance with Section 5.9.4(b)) and will bear its applicable percentage of the Net Loss set forth in the elected Profit Share Split (if applicable, as changed in accordance with Section 5.9.4(b)).
- 5.9.7. **Calculation**. Net Profit or Net Loss will be calculated for each [**], on a Profit Share Product-by-Profit Share Product basis, by adding the Net Sales of each Profit Share Product in the Territory and the Sublicense Revenue for such Profit Share Product for such [**], and subtracting the Program Expenses with respect to such Profit Share Product during such [**] from the sum of such Net Sales and Sublicense Revenue (to the extent not already deducted from Net Sales).
- 5.9.8. Payment of Expenses; Summary Statements. Subject to reconciliation in accordance with Section 5.9.9, the Party initially incurring Program Expenses will be responsible for and pay for all such Program Expenses so incurred. Each Party will report all Program Expenses, and Vertex will report all Sublicense Revenue and Net Sales in accordance with the terms and conditions hereof and in accordance with GAAP. If any Program Expenses relate to multiple Products, the Parties will work together to determine an equitable allocation of such Program Expenses between such Products. Within [**] after the end of each [**], each Party will submit to the other a written report reflecting. on a Profit Share Product-by-Profit Share Product basis, the estimated Program Expenses, Sublicense Revenue and Net Sales during the just-ended [**], except that each Party's submission for the last month of such [**] will be a good faith estimate and not actual amounts (each, a "Summary Statement"). Within [**] after the end of each [**], each Party will submit to the other an updated Summary Statement reflecting, on a Profit Share Product-by-Profit Share Product basis, the actual Program Expenses, Sublicense Revenue and Net Sales for the last month of such [**], which Summary Statement will be certified as true and accurate by a representative of such Party that is a Vice President of Finance or more senior representative. Each Summary Statement (after the initial Summary Statement) will reflect an adjustment for the actual amount of the previous [**] as needed; provided that, if, prior to preparation of a Summary Statement in accordance with the preceding sentence, a Party discovers that actual Program Expenses, Sublicense Revenue or Net Sales with respect to a Profit Share Product have deviated materially from any non-binding, good faith estimate of such Program Expenses, Sublicense Revenue or Net Sales submitted to the other Party in accordance with this Section 5.9.8

(including any deviation in any single Expense or in aggregate Sublicense Revenue or aggregate Net Sales, in each case, of more than \$[**]), then such Party shall promptly notify the other Party of such deviation in advance of delivery of such Summary Statement. Any reporting and reconciliation of variances between estimated and actual Expenses may be delayed by [**] as reasonably necessary in light of a Party's internal reporting procedures. The Parties' respective Summary Statements will serve as the basis of the Reconciliation Reports prepared by Vertex pursuant to Section 5.9.9. The Parties' respective finance departments, coordinated by the Alliance Managers, will meet at least [**], or as otherwise mutually agreed by the Parties, to discuss any questions or issues arising from the Summary Statements, including the basis for the recognition of specific Program Expenses, review cost estimates and forecasts, and discuss reconciliation and reporting procedures.

5.9.9. **Reconciliation**.

- (a) General Reconciliation. Vertex will prepare a reconciliation report, as soon as practicable, after the receipt of Company's updated Summary Statements, but in any event within [**] after the end of each [**], accompanied by reasonable supporting documents and calculations sufficient to support each Party's financial reporting obligations, independent auditor requirements and obligations under the Sarbanes-Oxley Act, which reconciles the amounts incurred and reported in each Party's Summary Statements and the share of the Net Profits and Net Losses to be allocated to each of the Parties for such [**] in accordance with Section 5.9.6, on a Profit Share Product-by- Profit Share Product basis and in the aggregate across all Profit Share Products (such report, the "Reconciliation Report").
- (b) Payment. Payment to reconcile aggregate Net Profit or Net Loss, as applicable, across all Profit Share Products shall be made by the owing Party to the other Party within [**] after such Reconciliation Report is delivered to Company. If Company does not pay any amount owed under this Section 5.9.9(b) within such [**] period, then Vertex may deliver written notice of such payment default to Company. Notwithstanding anything to the contrary in this Agreement, if Company does not cure such payment default within [**] following the date of such notice, then Vertex shall have the right, upon further written notice to Company and without limitation to any other right or remedy available to Vertex, to deem the Opt-Out to be exercised, and the Opt-Out Effective Date shall be deemed to be the date of such further written notice.

5.10. Payment Terms.

- 5.10.1. **Currency; Payment Method**. All payments under this Agreement are expressed in U.S. Dollars and will be paid in U.S. Dollars, by wire transfer or Automated Clearing House (ACH) payment to an account designated by the payee Party (which account may be updated from time to time by written notice to the other Party).
- 5.10.2. **Exchange**. If any amounts that are relevant to the determination of amounts to be paid under this Agreement or any calculations to be performed under this Agreement are denoted in a currency other than U.S. Dollars, such amounts will be converted to their U.S. Dollar equivalent using the payor Party's then-current standard procedures and methodology, including its then-current standard exchange rate methodology for the translation of foreign currency expenses into U.S. Dollars or, in the case of Sublicensees, such similar methodology, consistently applied. Calculation of Net Sales will exclude hedging and foreign exchange gain or loss realized through a hedging program.

5.11. Withholding Tax.

- 5.11.1. **Required Withholding**. The payments by a Party (the "**Payor**") to the other Party (the "**Payee**") under this Agreement (each, a "**Payment**") shall be made free and clear of, and without withholding and deduction on account of, any and all taxes, except for any withholding and deduction of taxes (other than backup withholding) required by Applicable Law ("**Required Withholding**"). If any Required Withholding applies to a Payment, subject to Section 5.11.3, the Payor shall (a) make such Required Withholding with respect to such Payment, (b) pay the amount of such Required Withholding to the appropriate Governmental Authority and (c) send evidence of the obligation together with proof of tax payment to the Payee on a reasonable and timely basis following such tax payment. Subject to Section 5.11.3, any Required Withholding made in accordance with the preceding sentence shall be treated as paid to the Payee for all purposes of this Agreement.
- 5.11.2. Cooperation. The Parties acknowledge that, under United States federal income tax law as in effect as of the Effective Date, no Required Withholding applies on account of United States federal nonresident withholding taxes with respect to a Payment to a Payee hereunder; provided that such Payee has, prior to the making of such Payment, provided to the Payor a properly completed and validly executed Internal Revenue Service Form W-9 that remains in effect. If a Payor determines that Required Withholding applies to a Payment, the Payor shall notify the Payee of such determination no less than [**] prior to making such Payment. Each Party agrees to cooperate with the other Party in (a) obtaining any reductions of or exemptions from any Required Withholding under Applicable Law (including any income tax treaty then in effect) and (b) claiming any refund of amounts of Required

Withholding withheld and paid to a Governmental Authority hereunder. Such cooperation shall include the providing and periodic updating or confirming of the continued validity of any required withholding certificates and tax residency certificates, if applicable.

- Additional Amounts. Notwithstanding Section 5.11.1, the following additional payments (each, an 5.11.3. "Additional Amount") shall be made, if applicable, by the respective Payor if one or both of the Parties undergoes a redomiciliation or assigns its respective rights or obligations under this Agreement (any such redomiciliation or assignment, a "Tax Action", and any such Party an "Acting Party") and, as a result of such Tax Action, the amount of Required Withholding is greater than the amount of Required Withholding absent such Tax Action. If the Payor is not the Acting Party, no Additional Amount shall be payable by the Payor. If the Payor is the Acting Party, then the Payor shall pay an Additional Amount such that, after the Required Withholding (including in respect of any Additional Amount), the Payee receives an amount equal to the amount it would have received had such Tax Action by the Payor not occurred. The obligation for the Payor to pay an Additional Amount pursuant to the preceding sentence shall not apply to the extent the Additional Amount (a) would not have been payable but for a Tax Action taken by the Payee or (b) is attributable to the failure by the Payee to comply with the requirements of this Section 5.11. For purposes of this Section 5.11, "redomiciliation" means a reincorporation in another jurisdiction or other action resulting in a change in tax residence of the Acting Party or its assignee. For the avoidance of doubt, this Section 5.11.3 shall not apply with respect to any backup withholding (or similar tax collection system under Applicable Law).
- 5.11.4. **Indirect Tax.** Notwithstanding anything to the contrary herein, all Payments are exclusive of any sales, use, value added, goods and services, gross receipts and similar turnover or gross margin taxes (together with any penalties and interest in respect thereof, "**Indirect Tax**"). If any amount of Indirect Tax is chargeable in respect of a Payment, the Payor shall pay such Indirect Tax at the applicable rate in respect of such Payment following the receipt of an invoice in the appropriate form from the Payee in respect of those Payments, such Indirect Tax to be payable on the later of (a) the due date of the payment of the Payment to which such Indirect Tax relates and (b) [**] after the receipt by the Payor of the applicable invoice setting forth the amount of the applicable Indirect Tax. The Parties will issue invoices for all amounts due under this Agreement consistent with applicable Indirect Tax requirements.

5.12. Records; Audits.

5.12.1. Vertex will keep and maintain accurate and complete records regarding all (a) Net Sales and Sublicense Revenue and (b) Program Expenses of

Vertex and its Affiliates for Profit Share Products (including Out-of-Pocket Expenses and FTE Costs), in each case ((a) and (b)), covering the [**]. Company will keep accurate and complete records regarding all (i) FTE Costs and Out-of-Pocket Costs incurred in connection with the performance of Research Activities and Additional Research Activities and (ii) if applicable, Company Activity Expenses incurred for Profit Share Products (including Out-of-Pocket Expenses and FTE Costs), in each case ((i) and (ii)), in sufficient detail to confirm the accuracy of any payments required under this Agreement and covering the [**].

Upon [**] prior written notice from the other Party (the "Auditing Party"), the Party required to 5.12.2. maintain records pursuant to Section 5.12.1 (as applicable, the "Audited Party") will permit an independent certified public accounting firm of internationally recognized standing, selected by the Auditing Party and reasonably acceptable to the Audited Party, to examine the relevant books and records of the Audited Party and its Affiliates, as may be reasonably necessary to verify (a) the Royalty Reports submitted by Vertex in accordance with Section 5.5.7. (b) the FTE Costs and Out-of-Pocket Costs reported by Company in accordance with Section 5.8.1 and Section 5.8.2, or (c) the Summary Statements and Reconciliation Reports submitted by the Parties pursuant to Section 5.9.8 and Section 5.9.9(a), as applicable (collectively, ((a)-(c)), "Reported Amounts"). An examination by the Auditing Party under this Section 5.12.2 will occur not more than [**] and will be limited to the pertinent books and records for any [**] ending not more than [**] before the date of the request. The accounting firm will be provided access to such books and records at the Audited Party's facility or facilities where such books and records are normally kept and such examination will be conducted during the Audited Party's normal business hours. The Audited Party may require the accounting firm to sign a customary non-disclosure agreement before providing the accounting firm access to its facilities or records. Upon completion of the audit, the accounting firm will provide both Parties a written report disclosing whether the Reported Amounts are correct or incorrect and the specific details concerning any discrepancies. No other information will be provided to the Auditing Party. If the Reported Amounts submitted by the Audited Party resulted in an underpayment or overpayment, the Party owing the underpaid or overpaid amount will promptly pay such amount to the other Party. The costs and fees of any audit conducted by the Auditing Party under this Section 5.12.2 will be borne by the Auditing Party, unless such audit reveals an underpayment of amounts owed to the or an overpayment of amounts owed by the Auditing Party of more than [**] percent of the amount that was owed by the Audited Party or owed to the Audited Party, as applicable, with respect to the relevant period, in which case, the Audited Party will reimburse the Auditing Party for the reasonable expense incurred by the Auditing Party in connection with the audit.

ARTICLE 6. INTELLECTUAL PROPERTY

- 6.1. Ownership of Agreement Technology. For purposes of determining ownership under this Section 6.1, inventorship will be determined in accordance with United States patent laws (regardless of where the applicable activities occurred).
 - 6.1.1. **Company Ownership**. As between the Parties, Company will be the sole owner of Company Agreement Technology and Company System Technology, and will retain all of its rights thereto, subject to any rights or licenses expressly granted by Company to Vertex or its Affiliates under this Agreement. Company will disclose to Vertex, and will cause its Affiliates to so disclose, potential inventions within the Company Agreement Know-How that constitute Licensed Technology quarterly at meetings of the IP Committee and in any event reasonably in advance of filing patent applications on any such inventions.
 - 6.1.2. **Vertex Ownership**. As between the Parties, Vertex will be the sole owner of Vertex Agreement Technology and Vertex System Technology, and will retain all of its rights thereto, subject to any rights or licenses expressly granted by Vertex to Company or its Affiliates under this Agreement.
 - 6.1.3. **Joint Ownership**. Joint Agreement Technology will be owned jointly by Vertex and Company on an equal and undivided basis, including all rights thereto, subject to any rights or licenses expressly granted by one Party to the other Party under this Agreement. Except as expressly provided in this Agreement, neither Party will have any obligation to account to the other for profits with respect to, or to obtain any consent of the other Party to license or exploit, Joint Agreement Technology by reason of joint ownership thereof, and each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting. Each Party, on behalf of itself and its respective Affiliates, shall assign and hereby assigns to the other Party, without additional compensation, its right, title and interest in and to any Joint Agreement Technology to the extent necessary to effect joint ownership of the Joint Agreement Technology as set forth in this Section 6.1.3.
 - 6.1.4. Disclosure and Assignment of Company System Technology and Vertex System Technology.
 - (a) Vertex will disclose to Company, and will cause its Affiliates to so disclose, potential inventions within the Company System Know-How and Overlapping Improvements, in each case, [**] at meetings of the IP Committee (and, with respect to inventions within the Overlapping Improvements, in any event reasonably in advance of filing patent applications on any such inventions). Vertex, on behalf

- of itself and its Affiliates, shall assign and hereby assigns to Company, without additional compensation, its right, title and interest in and to any Company System Technology.
- (b) Company will disclose to Vertex, and will cause its Affiliates to so disclose, potential inventions within the Vertex System Know-How and Overlapping Improvements, in each case, [**] at meetings of the IP Committee (and, with respect to inventions within the Overlapping Improvements, in any event reasonably in advance of filing patent applications on any such inventions). Company, on behalf of itself and its Affiliates, shall assign and hereby assigns to Vertex, without additional compensation, its right, title and interest in and to any Vertex System Technology.

6.2. **Prosecution and Maintenance of Patents**.

- 6.2.1. Company Agreement Patents and Company System Patents. As between the Parties, Company will have the sole right, at Company's expense, to control the preparation and filing ("Filing") of the Company Agreement Patents and Company System Patents. Subject to Section 6.2.4, following Filing, Company will have the sole right, at Company's expense, to control the Prosecution and Maintenance of the Company Agreement Patents and Company System Patents. The Parties agree to cooperate, through the IP Committee, to implement reasonable Prosecution and Maintenance strategies so that, to the extent reasonable, Company Agreement Patents, Company System Patents and Joint Agreement Patents including subject matter relating to (a) the composition, method of manufacture or method of use of one or more Licensed Agents or Products; (b) [**]; or (c) without limitation to clause (a), [**]; in each case ((a)-(c)), include solely such subject matter, so that such Patents are included within the [**].
- 6.2.2. **Vertex Agreement Patents and Vertex System Patents**. As between the Parties, Vertex will have the sole right, at Vertex's expense, to control the Prosecution and Maintenance of the Vertex Agreement Patents and Vertex System Patents.
- 6.2.3. **Joint Agreement Patents**. As between the Parties, the Parties shall jointly determine, in good faith, which Party will control (and be responsible for expenses with respect to) the Prosecution and Maintenance of the Joint Agreement Patents, taking into account, for each Joint Agreement Patent (a) the subject matter of such Joint Agreement Patent, (b) the degree of contribution to the inventive subject matter of such Joint Agreement Patent and (c) the relevance of such subject matter to each Party's business.
- 6.2.4. [**].

- (a) Notwithstanding Section 6.2.1 or Section 6.2.3, with respect to any Company Agreement Patent, Company System Patent or Joint Agreement Patent that solely claims Know-How included in the [**] (each, an "[**]"), Vertex shall have the right to elect, upon written notice to Company any time after Filing of such [**], to control the Prosecution and Maintenance of such [**] at its own expense. Upon such election, Company will cooperate and assist in transitioning the Prosecution and Maintenance of the applicable [**] to Vertex. If Vertex assumes Prosecution and Maintenance of any [**], then, without limitation to Section 6.2.6, Vertex will keep Company reasonably informed, and provide Company with a reasonable opportunity to comment on materials filings, with respect to such Prosecution and Maintenance. Company may elect to assign its rights, title and interest in any [**] to Vertex subject to the understanding that Vertex shall be restricted to prosecuting claims therein only to [**]; however, in such case the assigned [**] will continue to be deemed Licensed Patents under this Agreement for all other purposes.
- (b) If Vertex decides to abandon any [**], then Vertex will provide Company with notice at least [**] prior to the date such abandonment would become effective. Following such notice, Company shall have the right to elect, upon written notice to Vertex, to control the Prosecution and Maintenance of such [**] at its own expense. Upon such election, Vertex will cooperate and assist in transitioning the Prosecution and Maintenance of the applicable [**] to Company, and if, prior to such election, Company assigned its rights, title, and interest in the applicable [**] to Vertex, Vertex will assign those rights back to Company (provided that Vertex will retain its rights, title, and interest under Section 6.1.3 if the applicable [**] is a Joint Agreement Patent). If Company assumes Prosecution and Maintenance of any [**], then, without limitation to Section 6.2.6, Company will keep Vertex reasonably informed, and provide Vertex with a reasonable opportunity to comment on materials filings, with respect to such Prosecution and Maintenance.
- 6.2.5. **Cooperation**. Vertex and Company (and their respective Affiliates) will cooperate, and obtain the cooperation of their respective employees or obligated Third Parties that are inventors, in the Prosecution and Maintenance of any Company Agreement Patents, Vertex Agreement Patents, Joint Agreement Patents, Company System Patents or Vertex System Patents, including with respect to confirmatory assignments and inventor declarations. The Parties agree to work together in good faith to divide out claims into separate patent applications, to the extent reasonable without compromising [**] or the overall strength of the Patent portfolio with respect to Licensed Agents or Products, to allow for (a) sole ownership of patent applications and (b) partitioning of inventive

subject matter to align with the scope of the licenses set forth in this Agreement so as to separate inventions that would fall outside, from those that would fall within, the scope of the licenses set forth in this Agreement.

- 6.2.6. **IP Committee**. During the Term, each Party will keep the other Party informed through the IP Committee (or to the other Party, if the IP Committee is disbanded) as to material developments with respect to the Prosecution and Maintenance of Patents for which such Party has responsibility for Prosecution and Maintenance pursuant to this Section 6.2 that are exclusively licensed under this Agreement to the other Party, including by providing copies of any office actions or office action responses or other correspondence that such Party provides to or receives from any patent office, including notice of all interferences, reissues, re-examinations, or oppositions, and all patent-related filings within a reasonable time after such receiving or filing such documents, and by providing the other Party the timely opportunity to have reasonable input into the strategic aspects of such Prosecution and Maintenance with the understanding that, to the extent feasible, providing [**] for the receiving Party to consider and provide input shall be considered reasonable.
- 6.3. Defense of Claims Brought by Third Parties. If any Third Party brings a claim or otherwise asserts that a Licensed Agent or Product infringes such Third Party's Patent or misappropriates such Third Party's Know-How (each, a "Third Party Infringement Claim"), the Party first having notice of the claim or assertion will promptly notify the other Party in writing. Subject to Section 8.1, Vertex will have the sole right to undertake and control the defense or settlement of any Third Party Infringement Claim using counsel of its choice, at its expense. Subject to Section 8.1, if Company is named as a defendant in any such Third Party Infringement Claim, Company will have the right to participate in such defense and settlement with its own counsel, at its expense. Subject to Section 8.1, Vertex will not enter into any settlement of any Third Party Infringement Claim that is instituted or threatened to be instituted against Company without Company's prior written consent, which will not be unreasonably withheld, conditioned or delayed; provided that, such consent will not be required if such settlement includes a release of all liability in favor of Company or an assumption of any unreleased liability by Vertex without any admission of liability by the Company. As requested by Vertex, Company will provide reasonable cooperation and assistance to Vertex in connection with Vertex's control of the defense or settlement of a Third Party Infringement Claim. Such cooperation and assistance will include executing all necessary and proper documents and taking such actions as will be appropriate to allow Vertex to control the defense and settlement of such Third Party Infringement Claim. Subject to Section 8.1, Vertex will reimburse Company for the reasonable Out-of-Pocket Costs incurred by Company in providing such assistance and cooperation; provided that Vertex will have no obligation to reimburse Company for any such Out-of-Pocket Costs incurred if Company exercises its right to participate in the defense and settlement of a Third Party Infringement Claim with

its own counsel. Vertex will keep Company reasonably informed of the progress of any Third Party Infringement Claim. To the extent reasonable, both Parties will cooperate in good faith to (i) ensure that Vertex has the ability to continue to Commercialize Products and (ii) avoid or minimize any additional royalties on Products.

6.4. Enforcement Against Competitive Infringement.

6.4.1. **Duty to Notify of Competitive Infringement**. If either Party learns of a Competitive Infringement, such Party will promptly notify the other Party in writing and will provide such other Party with available information regarding such Competitive Infringement.

6.4.2. **Enforcement**.

- (a) Vertex will have the first right, but not the obligation, to institute, prosecute, and control a Proceeding to enforce the [**] and Joint Agreement Technology, in each case, with respect to any Competitive Infringement by counsel of its own choice, at its own expense (unless such Competitive Infringement relates to a Profit Share Product, in which case such expenses will be deemed to be Patent Enforcement Expenses). If Vertex does not initiate a Proceeding within [**] after written notice of such Competitive Infringement is first provided by a Party under Section 6.4.1, Company will have the right to initiate and control a Proceeding with respect to such Competitive Infringement by counsel of its own choice, at its own expense and Vertex will have the right, at its own expense, to be represented in any such action by counsel of its own choice; *provided* that if Vertex notifies Company during such [**] period that it is electing in good faith not to institute any Proceeding against such Competitive Infringement for strategic reasons, Company will not have the right to initiate and control any Proceeding with respect to such Competitive Infringement.
- (b) Except as set forth below, Company will have the sole right, but not the obligation, to institute, prosecute, and control a Proceeding with respect to any Competitive Infringement involving any Licensed Technology other than the [**] or Joint Agreement Technology by counsel of its own choice, at its own expense (unless such Competitive Infringement relates to a Profit Share Product, in which case such expenses will be deemed to be Patent Enforcement Expenses). Notwithstanding the foregoing, upon Vertex's request, (i) Company will be obligated to institute, prosecute, and control a Proceeding with respect to any Competitive Infringement involving any Licensed Technology other than the [**] or Joint Agreement Technology in the event that the Competitive Infringement involves only Licensed Technology that is not [**] or Joint Agreement

Technology and (ii) Company will not unreasonably refuse to institute, prosecute, and control a Proceeding with respect to any Competitive Infringement involving any Licensed Technology; provided, however, that in no event will Company be obligated to initiate, prosecute or control any Proceeding against [**] or its Affiliates (or any Person receiving a sublicense from them) with respect to the practice of any Licensed Technology to the extent [**].

(c) The Party prosecuting and controlling any Proceeding with respect to any Competitive Infringement will (i) keep the other Party reasonably apprised of the progress of such Proceeding, (ii) reasonably consider the other Party's comments with respect to the conduct of such Proceeding and (iii) not enter into a settlement, consent judgment or other voluntary final disposition of such Proceeding that disclaims, limits the scope of, admits the invalidity or unenforceability of, or grants a license, covenant not to sue, or similar immunity that has an adverse effect on the other Party's rights hereunder without the other Party's prior written consent, not to be unreasonably withheld; *provided* that the foregoing restriction on granting a license under this clause (iii) will not apply with respect to any Sublicense granted by Vertex.

6.4.3. Joinder.

- (a) If a Party initiates a Proceeding in accordance with this Section 6.4, the other Party agrees to be joined as a party plaintiff where necessary and to give the first Party reasonable assistance and authority to file and prosecute the Proceeding. Subject to Section 6.4.4, the Out-of-Pocket Costs of each Party incurred pursuant to this Section 6.4.3(a) will be borne by the Party initiating such Proceeding (and, for clarity, any such costs of Company reimbursed by Vertex under this Section 6.4.3(a) with respect to any Competitive Infringement that relates to a Profit Share Product shall be deemed to be Patent Enforcement Expenses).
- (b) If one Party initiates a Proceeding in accordance with this Section 6.4, the other Party may join such Proceeding as a party plaintiff where necessary for such other Party to seek lost profits with respect to such infringement.
- 6.4.4. **Share of Recoveries**. Any damages or other monetary awards recovered with respect to a Proceeding brought pursuant to this Section 6.4 will be shared as follows:
 - (a) the amount of such recovery will first be applied to the Parties' reasonable Out-of-Pocket Costs incurred in connection with such

- Proceeding (which amounts will be allocated *pro rata* if insufficient to cover the totality of such expenses); then
- (b) any remaining proceeds constituting direct or actual damages for acts of infringement will be paid to, or retained by, Vertex; *provided* that such amounts will be included in Net Sales for the [**] in which such amounts are received by Vertex; and
- (c) any remaining proceeds constituting punitive or treble damages will be allocated between the Parties as follows: in the case of a Royalty Product, Vertex will retain [**]% of such proceeds and Company will receive [**]% of such proceeds and in the case of a Profit Share Product, such proceeds shall be deemed Net Sales.
- 6.4.5. **Settlement**. Notwithstanding anything to the contrary under this ARTICLE 6, neither Party may enter a settlement, consent judgment or other voluntary final disposition of a suit under this ARTICLE 6 that disclaims, limits the scope of, admits the invalidity or unenforceability of, or grants a license, covenant not to sue or similar immunity under a Patent Controlled by the other Party or its Affiliates without first obtaining the written consent of the Party that Controls (or whose Affiliate Controls) the relevant Patent; *provided*, that the foregoing restriction on granting a license will not apply with respect to any Sublicense granted by Vertex.

6.5. **Other Infringement**.

- 6.5.1. **Joint Agreement Patents**. With respect to the infringement of a Joint Agreement Patent that is not a Competitive Infringement, neither Party shall enforce any Joint Agreement Patent unless mutually agreed by the Parties; *provided* that the Parties will cooperate in good faith to bring suit together against the applicable Third Party infringer or the Parties may decide to permit one Party to solely bring suit. Any damages or other monetary awards recovered with respect to a Proceeding brought pursuant to this Section 6.5.1 will be shared as follows: (a) the amount of such recovery will first be applied to the Parties' reasonable Out-of-Pocket Costs incurred in connection with such Proceeding (which amounts will be allocated *pro rata* if insufficient to cover the totality of such expenses); then (b) any remaining proceeds will be allocated as follows: (i) if the Parties jointly initiate the applicable Proceeding pursuant to this Section 6.5.1, each Party will be allocated [**]% of such proceeds; and (ii) if only one Party initiates the applicable Proceeding pursuant to this Section 6.5.1, such Party will retain [**]% of such proceeds and the other Party will receive [**]% of such proceeds.
- 6.5.2. **Patents Solely Owned by Company**. Company will retain all rights to pursue an infringement of any Patent solely owned by Company that is

- not a Competitive Infringement and Company will retain all recoveries with respect thereto.
- 6.5.3. **Patents Solely Owned by Vertex**. Vertex will retain all rights to pursue an infringement of any Patent solely owned by Vertex and Vertex will retain all recoveries with respect thereto.
- 6.6. Patent Listing. Vertex will have the sole right, but not the obligation, to submit to all applicable Regulatory Authorities patent information pertaining to each applicable Product pursuant to 21 U.S.C. § 355(b)(1)(G), any similar statutory or regulatory requirement enacted in the future regarding biologic products, or any similar statutory or regulatory requirement in any non-U.S. country or other regulatory jurisdiction.
- 6.7. Common Ownership Legislation. Notwithstanding anything to the contrary in this ARTICLE 6, neither Party will have the right to make an election under the Common Ownership Legislation when exercising its rights under this ARTICLE 6 without the prior written consent of the other Party, which will not be unreasonably withheld, conditioned or delayed. With respect to any such permitted election, the Parties will use reasonable efforts to cooperate and coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the Common Ownership Legislation. Notwithstanding the foregoing, the other Party's consent under this Section 6.7 will not be required in connection with an obviousness-type double patenting rejection in any patent application claiming a Licensed Agent, Product, or uses thereof.
- 6.8. Patent Term Extension. Vertex will have the sole right to obtain patent term restoration in any country in the Territory under any statute or regulation equivalent or similar to 35 U.S.C. § 156, where applicable to a Product. Vertex will determine which relevant patents (including Licensed Patents) will be extended (including by filing supplementary protection certificates and any other extensions that are now or in the future become available); provided, however, that Vertex may not elect to extend a Patent Controlled by Company or its Affiliates that is not an [**] without Company's prior written consent. Company will abide by Vertex's determination and cooperate, as reasonably requested by Vertex, in connection with the foregoing (including by providing appropriate information and executing appropriate documents).
- 6.9. **Recording**. If Vertex deems it necessary or desirable to register or record this Agreement or evidence of this Agreement with any patent office or other appropriate Governmental Authority in one or more jurisdictions in the Territory, Company will reasonably cooperate to execute and deliver to Vertex any documents accurately reflecting or evidencing this Agreement that are necessary or desirable, in Vertex's reasonable judgment, to complete such registration or recordation. Vertex will reimburse Company for all reasonable Out-of-Pocket

Costs, including attorneys' fees, incurred by Company in complying with the provisions of this Section 6.9.

- 6.10. <u>Unitary Patent System</u>. The Party Prosecuting and Maintaining a Patent in Europe pursuant to Section 6.2 will have the exclusive right to opt-in or opt-out of the Europe Unitary Patent System for such Patent. For clarity, "to opt-in or opt-out" refers to both the right to have or have not a European patent application or an issued European patent registered to have unitary effect within the meaning of Regulation (EU) No 1257/2012 of December 17, 2012 as well as the Agreement on a Unified Patent Court as of February 19, 2013; and to the right to opt-in or opt-out from the exclusive competence of the Unified Patent Court in accordance with Article 83(3) of that Agreement on a Unified Patent Court. Without limiting the generality of the foregoing, unless a Party or its Affiliate has expressly opted in to the Europe Unitary Patent System with respect to a given Patent, the other Party will not initiate any action with respect to such Patent under the Europe Unitary Patent System without such Party's prior written approval, such approval to be granted or withheld in such Party's sole discretion.
- 6.11. <u>Trademarks</u>. As between the Parties, all trademarks and trade dress rights used in connection with the Commercialization of the Products in the Field in the Territory will be owned exclusively by Vertex.

6.12. **Bankruptcy**.

All rights and licenses now or hereafter granted by Company to Vertex under or pursuant to this 6.12.1. Agreement, including, for the avoidance of doubt, the licenses granted to Vertex pursuant to Section 4.1, are, for all purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined in the U.S. Bankruptcy Code. Upon the occurrence of any Insolvency Event with respect to Company, Company agrees that Vertex, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. Without limiting the generality of the foregoing, the Parties intend and agree that any sale of Company's assets under Section 363 of the Bankruptcy Code shall be subject to Vertex's rights under Section 365(n), that Vertex cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser "free and clear" of Vertex's rights under this Agreement and Section 365(n) without the express, contemporaneous consent of Vertex. Further, each Party agrees and acknowledges that all payments by Vertex to Company hereunder, other than the up-front fee pursuant to Section 5.1, royalty payments pursuant to Section 5.5, and the sales milestones pursuant to Section 5.4.2, do not constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code or relate to licenses of intellectual property hereunder. Company will, during the Term, create and maintain current copies or, if not amenable to copying,

detailed descriptions or other appropriate embodiments, to the extent feasible, of all intellectual property licensed under this Agreement. Each Party acknowledges and agrees that "embodiments" of intellectual property within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples and inventory, research studies and data, all Regulatory Approvals (and all applications for Regulatory Approval) and rights of reference therein, the Licensed Technology and all information related to the Licensed Technology. If (x) a case under the U.S. Bankruptcy Code is commenced by or against Company, (y) this Agreement is rejected as provided in the U.S. Bankruptcy Code, and (z) Vertex elects to retain its rights hereunder as provided in Section 365(n) of the U.S. Bankruptcy Code, Company (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) will:

- (a) provide Vertex with all such intellectual property (including all embodiments thereof) held by Company and such successors and assigns, or otherwise available to them, immediately upon Vertex's written request. Whenever Company or any of its successors or assigns provides to Vertex any of the intellectual property licensed hereunder (or any embodiment thereof) pursuant to this Section 6.12.1(a), Vertex will have the right to perform Company's obligations hereunder with respect to such intellectual property, but neither such provision nor such performance by Vertex will release Company from liability resulting from rejection of the license or the failure to perform such obligations; and
- (b) not interfere with Vertex's rights under this Agreement, or any agreement supplemental hereto, to such intellectual property (including such embodiments), including any right to obtain such intellectual property (or such embodiments) from another entity, to the extent provided in Section 365(n) of the U.S. Bankruptcy Code.
- 6.12.2. All rights, powers and remedies of Vertex provided herein are in addition to and not in substitution for any other rights, powers and remedies now or hereafter existing at law or in equity (including the U.S. Bankruptcy Code) in the event of the commencement of a case under the U.S. Bankruptcy Code with respect to Company. The Parties intend the following rights to extend to the maximum extent permitted by Applicable Law, and to be enforceable under U.S. Bankruptcy Code Section 365(n):
 - (a) the right of access to any intellectual property rights (including all embodiments thereof) of Company, or any Third Party with whom Company contracts to perform an obligation of Company under this Agreement, and, in the case of any such Third Party, which is necessary for the Exploitation of Licensed Agents and Products; and

(b) the right to contract directly with any Third Party to complete the contracted work.

ARTICLE 7. REPRESENTATIONS AND WARRANTIES

- 7.1. **Representations and Warranties of Vertex**. Vertex hereby represents and warrants to Company, as of the Effective Date, that:
 - 7.1.1. it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization;
 - 7.1.2. it (a) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;
 - 7.1.3. this Agreement has been duly executed and delivered on behalf of Vertex, and constitutes a legal, valid and binding obligation, enforceable against Vertex in accordance with the terms hereof;
 - 7.1.4. the execution, delivery and performance of this Agreement by Vertex will not constitute a default under or conflict with any agreement, instrument, obligation or understanding, oral or written, to which either entity is a party or by which either entity is bound, or violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and
 - 7.1.5. it has obtained all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons or entities required to be obtained by it in connection with the execution and delivery of this Agreement.
- 7.2. **Representations and Warranties of Company**. Company hereby represents and warrants to Vertex, that as of the Effective Date:
 - 7.2.1. it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization;
 - 7.2.2. it (a) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;
 - 7.2.3. it has the requisite resources and expertise to perform its obligations hereunder;

- 7.2.4. this Agreement has been duly executed and delivered on behalf of Company, and constitutes a legal, valid and binding obligation, enforceable against it in accordance with the terms hereof;
- 7.2.5. the execution, delivery and performance of this Agreement by Company will not constitute a default under or conflict with any agreement, instrument, obligation or understanding, oral or written, to which it is a party or by which it is bound, or violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it;
- 7.2.6. it has obtained all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons or entities required to be obtained by it in connection with the execution and delivery of this Agreement;
- 7.2.7. to Company's Knowledge, the Patents and Know-How intended as of the Effective Date to be used or practiced by or on behalf of Company in the Research Activities under the initial Research Plan with respect to any Company Delivery System or Company Gene Editing System are Controlled by Company and included in the Licensed Technology;
- 7.2.8. Company is the sole and exclusive owner or exclusive licensee of the Licensed Patents other than the Licensed Patents in-licensed by Company under the Existing In-License Agreement, all of which are free and clear of any liens, charges and encumbrances, and, as of the Effective Date, neither any license granted by Company or its Affiliates to any Third Party, nor any agreement between any Third Party and Company or its Affiliates, conflicts with the licenses or other rights granted to Vertex hereunder and Company is entitled to grant all rights and licenses (or sublicenses, as the case may be) it purports to grant to Vertex under this Agreement;
- 7.2.9. Company has disclosed to Vertex in <u>Schedule 1.118</u> all Licensed Patents existing as of the Effective Date;
- 7.2.10. to Company's Knowledge, the Licensed Patents are subsisting and are, or, upon issuance, will be, valid and enforceable patents and no Third Party has challenged the scope, validity or enforceability of such Patents (including by way of example through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign Governmental Authority);
- 7.2.11. to Company's Knowledge, no Third Party is infringing or threatening to infringe any of the Licensed Patents or misappropriating or threatening to misappropriate any Licensed Know-How;

- 7.2.12. it has complied with Applicable Law, including any disclosure requirements of the United States Patent and Trademark Office or any analogous foreign Governmental Authority, in connection with the Prosecution and Maintenance of the Licensed Patents and has timely paid all filing and renewal fees payable with respect to any such Patents for which it controls Prosecution and Maintenance;
- 7.2.13. it has obtained assignments from the inventors of all inventorship rights relating to the Licensed Patents other than the Licensed Patents in-licensed by Company under the Existing In-License Agreement, and all such assignments of inventorship rights relating to such Patents are valid and enforceable;
- 7.2.14. except for the Existing In-License Agreement, there is no agreement between Company or any of its Affiliates and any Third Party pursuant to which Company or its Affiliate has acquired, in-licensed or otherwise Controls any Patents or Know-How that, to Company's Knowledge, will be used or practiced in the Research Activities under the initial Research Plan. The Existing In-License Agreement is in full force and effect and has not been modified or amended (other than such modifications or amendments identified in Schedule 5.7.1-1). Company has provided a true and complete copy of the Existing In-License Agreement, and any amendments thereto, to Vertex. Neither Company nor its Affiliates nor, to the best of its knowledge, the Third Party licensor in the Existing In-License Agreement is in material breach of, or in default with respect to a material obligation thereunder, and neither such party has claimed or has grounds upon which to claim that the other party is in material breach of, or in default with respect to a material obligation thereunder;
- 7.2.15. Company and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all Licensed Know-How that constitutes trade secrets under Applicable Law (including requiring all employees, consultants and independent contractors to execute binding and enforceable agreements requiring all such employees, consultants and independent contractors to maintain the confidentiality of such Licensed Know-How) and, to Company's Knowledge, such Licensed Know-How has not been used, disclosed to or discovered by any Third Party except pursuant to such confidentiality agreements and there has not been a breach by any party to such confidentiality agreements;
- 7.2.16. (a) no Licensed Technology owned by Company or its Affiliates is subject to any funding agreement with any government or governmental agency and (b) to Company's Knowledge, no other Licensed Technology is subject to any funding agreement with any government or governmental agency;

- 7.2.17. to Company's Knowledge, the composition of [**] alone (individually, not in combination or part of a formulation with other components) does not and will not infringe any issued Patent of any Third Party or, if and when issued, any claim within any Patent application of any Third Party; except that no such representation or warranty is made with respect to any Patent in-licensed by Company under the Existing In-License Agreement;
- 7.2.18. (a) the conception, development, and reduction to practice of the Licensed Technology have not constituted or involved the misappropriation of any trade secret of any Third Party or breach of any confidentiality obligation the Company has to a Third Party, and (b) the practice of the Licensed Know-How in the making, having made, using, selling, offering for sale, importing, exporting or other exploitation (including researching, developing, manufacturing or commercializing) by Company or Vertex (or their respective Affiliates or Sublicensees) of a Company Delivery System or Company Gene Editing System as contemplated by this Agreement does not and will not constitute a misappropriation of any trade secret of any Third Party or breach of any confidentiality obligation that Company has to Third Party;
- 7.2.19. there are no judgments or settlements against or owed by Company or its Affiliates or, to its knowledge, pending or threatened claims or litigation, in either case relating to the Licensed Technology or any Company Delivery System or Company Gene Editing System;
- 7.2.20. there is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the best of its knowledge, threatened against Company, any of its Affiliates or any Third Party, in each case in connection with the Licensed Technology, any Company Delivery System or any Company Gene Editing System, or otherwise relating to the transactions contemplated by this Agreement;
- 7.2.21. Company has not employed (and, to the best of its knowledge, has not used a contractor or consultant that has employed) any Person debarred by the FDA (or subject to a similar sanction of EMA or foreign equivalent), or any Person that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA or foreign equivalent), in any capacity in connection with this Agreement;
- 7.2.22. with respect to any Licensed Technology, Company Delivery System, Company Gene Editing System or activities to be performed by Company in connection with this Agreement, Company has not taken any action directly or indirectly to unlawfully offer, promise, or pay, or authorize the offer or payment of, any money or anything of value in order to improperly or corruptly seek to influence any Government Official or any

- other person in order to gain an improper advantage, and has not accepted any such unlawful payment;
- 7.2.23. to its knowledge, except to the extent permissible under United States law, neither Company nor any of its Affiliates has, on its own behalf or in acting on behalf of any other Person, directly engaged in any transaction, or has otherwise dealt with, any country or Person targeted by the United States, Europe or other relevant economic sanctions laws in connection with any activities contemplated by this Agreement;
- 7.2.24. [**].
- 7.3. <u>Mutual Covenants</u>: Each Party hereby covenants to the other Party that, except as expressly permitted under this Agreement:
 - 7.3.1. such Party will, and will require its Affiliates and Subcontractors to, materially comply with Applicable Law and accepted pharmaceutical industry business practices in conducting its activities hereunder, including (a) to the extent applicable, the FD&C Act, the Anti-Kickback Statute (42 U.S.C. 1320a-7b), Civil Monetary Penalty Statute (42 U.S.C. 1320a-7a), the False Claims Act (31 U.S.C. 3729 et seq.), comparable state statutes, the regulations promulgated under all such statutes and the regulations issued by the FDA, consistent with the 'Compliance Program Guidance for Pharmaceutical Manufacturers' published by the Office of Inspector General, U.S. Department of Health and Human Services, (b) the applicable laws and regulations of the countries where it operates, including anti-bribery and anti-corruption laws, accounting and record keeping laws and laws relating to interactions with healthcare professionals or healthcare providers and Government Officials and (c) where appropriate GMP, GCP and GLP (or similar standards):
 - 7.3.2. all employees and Subcontractors of such Party performing Research Activities or Additional Research Activities hereunder on behalf of such Party will be obligated to assign all right, title and interest in and to any inventions Created by them, whether or not patentable, to such Party as the sole owner thereof; *provided* that (a) in the case of Vertex, this Section 7.3.2 shall apply only with respect to inventions included in the Company System Know-How and (b) in the case of Subcontractors, such assignment obligation shall apply only to the extent such inventions are included in the Company System Know-How or Vertex System Know-How and, with respect to any other inventions Created by Subcontractors, Company will use Commercially Reasonable Efforts to obtain such assignment obligation and, if after using such Commercially Reasonable Efforts, Company is not able to obtain such assignment obligation, then Company shall have the right to instead obtain an exclusive license under such inventions for purposes of researching, developing, manufacturing and commercializing [**] (and agents contained in such products) so that

- such inventions are Controlled by Company and included in the Licensed Technology and exclusively licensed to Vertex under this Agreement;
- 7.3.3. such Party will not engage directly or indirectly, in any capacity in connection with this Agreement any Person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any such similar sanction;
- 7.3.4. such Party will be, will cause its Affiliates to be, in material compliance with all applicable economics sanctions, import, and export control laws, regulations, and orders;
- 7.3.5. such Party will not, and will cause its Affiliates not to, engage with or engage in any transaction, or otherwise deal with, any country or Person targeted by the United States, Europe or other relevant economic sanctions laws in connection with any activities contemplated under this Agreement, in each case, except as permitted by Applicable Law; and
- 7.3.6. such Party will be, as between the Parties, solely responsible to ensure Compliance in all material respects by it and its Affiliates.
- 7.4. <u>Company Covenants</u>. Company hereby covenants to Vertex that, except as expressly permitted under this Agreement:
 - 7.4.1. Company will maintain and not materially breach (or breach in a manner that could reasonably give rise to a right for the respective counterparty to terminate), and will cause its Affiliates to maintain and not materially breach (or breach in a manner that could reasonably give rise to a right for the respective counterparty to terminate), any Company In-License Agreements and New Company Agreements;
 - 7.4.2. Company will promptly notify Vertex in writing of any material breach by Company or its Affiliate or a Third Party of any Company In-License Agreements or New Company Agreements, and will promptly notify Vertex in writing if Company or its Affiliate sends or receives a notice of material breach of any Company In-License Agreements or New Company Agreements, and in the event of a breach by Company or its Affiliate, will permit Vertex to cure such breach on Company's or its Affiliate's behalf upon Vertex's request;
 - 7.4.3. Company will not, and will cause its Affiliates not to, amend, modify or terminate any Company In-License Agreement in a manner that would adversely affect Vertex's rights hereunder (including, for clarity, exercising its right under the Existing In-License Agreement to remove [**] from the "Licensed Field" (as defined thereunder)) without first obtaining Vertex's written consent, which consent may be withheld in Vertex's sole discretion;

- 7.4.4. as of the date of delivery of any Materials to Vertex pursuant to this Agreement, Company has the right to deliver such Materials to Vertex for use as contemplated by this Agreement;
- 7.4.5. neither Company nor any of its Affiliates will effect any corporate restructuring or enter into any new agreement or otherwise obligate itself to any Third Party or Affiliate, or amend an existing agreement with a Third Party or Affiliate, in each case, in a manner that restricts, limits, or encumbers the rights granted to Vertex under this Agreement or the obligations of Company or its Affiliates under this Agreement;
- 7.4.6. Company will not, and will cause its Affiliates not to (a) license, sell, assign or otherwise transfer to any Person any Licensed Technology (or agree to do any of the foregoing), (b) negotiate with, offer to, or grant any license to any Person, or (c) incur or permit to exist, with respect to any Licensed Technology, any lien, encumbrance, charge, security interest, mortgage, liability, grant of license to Third Parties or other restriction (including in connection with any indebtedness), in each case ((a) through (c)), that would conflict with, limit, impair or restrict the rights and licenses granted to Vertex hereunder;
- 7.4.7. with respect to any Licensed Technology, Company Delivery System, Company Gene Editing System, Licensed Agent, Product, payments or activities performed by Company in connection with this Agreement, Company will not take any action to unlawfully offer, promise, or pay, or authorize the offer or payment of, any money or anything of value in order to improperly or corruptly seek to influence any Government Official or any other person in order to gain an improper advantage, and will not accept any such unlawful payment;
- 7.4.8. Company will inform Vertex in writing promptly if it or any Person engaged by Company or any of its Affiliates who is performing services under this Agreement or any ancillary agreements is debarred or is the subject of a conviction described in Section 306 of the FD&C Act, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to Company's knowledge, is threatened, relating to the debarment or conviction of Company, any of its Affiliates or any such Person performing services hereunder or thereunder; and
- 7.4.9. without limitation to any other provision of this Agreement, during the Term, Company will not, and will cause its Affiliates not to, permit [**].
- 7.5. **DISCLAIMER**. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY NOR ITS AFFILIATES MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

VERTEX AND COMPANY UNDERSTAND THAT EACH PRODUCT IS THE SUBJECT OF ONGOING RESEARCH AND DEVELOPMENT AND THAT NEITHER PARTY CAN ASSURE THE SAFETY, USEFULNESS OR COMMERCIAL OR TECHNICAL VIABILITY OF ANY PRODUCT.

ARTICLE 8. INDEMNIFICATION; INSURANCE; LIMITATIONS

8.1. **Indemnification**.

- 8.1.1. **Indemnification by Vertex**. Subject to Section 8.1.3, Vertex will indemnify Company, its Affiliates, and its and its Affiliates' employees, officers and directors (each, a "Company Indemnified Party") from and against any liability, loss, damage or expense (including reasonable attorneys' fees and expenses) (collectively, "Liability") that the Company Indemnified Party may incur or otherwise be required to pay to one or more Third Parties in connection with any Third Party suit, investigation, claim or demand ("Third Party Claim") resulting from or arising out of:
 - (a) the Exploitation of any Licensed Agent or Product by, on behalf of, or under the authority of, Vertex (other than by any Company Indemnified Party);
 - (b) the breach by Vertex of any of its representations, warranties or covenants set forth in this Agreement; or
 - (c) the gross negligence or intentional acts of Vertex or any other Vertex Indemnified Party;

and except, in each case ((a)–(c)), to the extent such Third Party Claim results from or arises out of an event described in clause (a) through (c) of Section 8.1.2, as to which Third Party Claim each Party shall indemnify the other to the extent of their respective liability.

- 8.1.2. **Indemnification by Company**. Subject to Section 8.1.3, Company will indemnify Vertex, its Affiliates and its and its Affiliates' employees, officers and directors, Sublicensees and Distributors (each, a "**Vertex Indemnified Party**") from and against any Liability that the Vertex Indemnified Party may incur or otherwise be required to pay to one or more Third Parties in connection with any Third Party Claim resulting from or arising out of:
 - (a) any claim that Licensed Know-How (i) utilized in the Research Activities, Additional Research Activities or Other Company Activities by or on behalf of Company or (ii) incorporated into a Company Delivery System or Company Gene Editing System by or on behalf of Company in the performance of the Research Activities, Additional Research Activities or Other Company Activities, in each case ((i) or (ii)), constituted, at the time such

- activities were performed, misappropriation of any trade secret owned or possessed by any Third Party or violation of confidentiality obligations owed to a Third Party;
- (b) the breach by Company of any of its representations, warranties or covenants set forth in this Agreement; or
- (c) the gross negligence or intentional acts of Company or any other Company Indemnified Party;

and except, in each case ((a)–(c)), to the extent such Third Party Claim results from or arises out of an event described in clause (a) through (c) of Section 8.1.1, as to which Third Party Claim each Party shall indemnify the other to the extent of their respective liability.

- 8.1.3. **Certain Liabilities**. Notwithstanding the foregoing, any Liability that a Vertex Indemnified Party or Company Indemnified Party may incur in connection with any Third Party Claim to the extent resulting from or arising out of the Exploitation of any Profit Share Product or any Licensed Agent contained in a Profit Share Product, in each case, which Third Party Claim results from or arises out of matters occurring during the period beginning on the Profit Share Effective Date and ending on the Opt-Out Effective Date, shall be deemed to be Other Out-of-Pocket Expenses, excluding any of the following Liability:
 - (a) with respect to any such Liability incurred by any Vertex Indemnified Party:
 - (i) any such Liability to the extent that Company provides indemnification pursuant to clause (a), (b) or (c) of Section 8.1.2;
 - (ii) any such Liability to the extent arising from or occurring as a result of an event described in clause (b) or (c) of Section 8.1.1; and
 - (b) with respect to any such Liability incurred by any Company Indemnified Party:
 - (i) any such Liability to the extent that Vertex provides indemnification pursuant to clause (b) or (c) of Section 8.1.1; and
 - (ii) any such Liability to the extent arising from or occurring as a result of any event described in clause (a), (b) or (c) of Section 8.1.2.
- 8.1.4. **Procedure**. Each Party will notify the other Party in writing if it becomes aware of a Third Party Claim for which such Party may seek

indemnification hereunder. If any Third Party Claim is instituted against a Party (or another Company Indemnified Party in the case of Company, or another Vertex Indemnified Party in the case of Vertex) with respect to which indemnity may be sought pursuant to Section 8.1.1, 8.1.2 or 8.1.3, as applicable, such Party (the "Indemnified Party") will give prompt written notice of the indemnity claim to the other Party (the "Indemnifying Party") and provide the Indemnifying Party with a copy of any complaint, summons or other written notice that the Company Indemnified Party or Vertex Indemnified Party, as applicable, receives in connection with any such Third Party Claim. An Indemnified Party's failure to deliver such written notice will relieve the Indemnifying Party of liability to the Company Indemnified Party or Vertex Indemnified Party, as applicable, under Section 8.1.1, 8.1.2 or 8.1.3, as applicable, only to the extent such delay is prejudicial to the Indemnifying Party's ability to defend such Third Party Claim. Provided that the Indemnifying Party is not contesting the indemnity obligation, the Company Indemnified Party or Vertex Indemnified Party, as applicable, will permit the Indemnifying Party to control any litigation relating to such Third Party Claim and the disposition of such Third Party Claim by negotiated settlement or otherwise (subject to this Section 8.1) and any failure to contest such obligation prior to assuming control will be deemed to be an admission of the obligation to indemnify. The Indemnifying Party will act reasonably and in good faith with respect to all matters relating to such Third Party Claim and will not settle or otherwise resolve such Third Party Claim without the prior written consent of the Company Indemnified Party or Vertex Indemnified Party, as applicable, which will not be unreasonably withheld, conditioned or delayed; provided that such consent will not be required with respect to any settlement involving only the payment of monetary awards (a) for which the Indemnifying Party will be fully responsible or (b) that are deemed to be Other Out-of-Pocket Expenses pursuant to Section 8.1.3. The Company Indemnified Party or Vertex Indemnified Party, as applicable, will cooperate with the Indemnifying Party in the Indemnifying Party's defense of any Third Party Claim for which indemnity is sought under this Agreement, at the Indemnifying Party's cost and expense (provided that with respect to any Third Party Claim addressed by Section 8.1.3, such cost and expense shall be deemed to be Other Out-of-Pocket Expenses).

8.2. **Insurance**. Throughout the Term and for [**] thereafter, each Party will respectively, at its cost, obtain and maintain the insurance coverage listed below from insurance carriers licensed to do business under the laws of the country, state, commonwealth, province or territory in which such Party's obligations are provided, with insurers that carry a rating of at least an A-VII or better from A.M. Best. Each Party will furnish to the other Party evidence of such insurance upon request. Notwithstanding the foregoing, Vertex may self-insure to the extent that it self-insures for its other activities.

INSURANCE TYPE	MINIMUM LIMITS	MINIMUM COVERAGE	RESPECTIVELY MUST BE MAINTAINED BY
Network Security and Privacy Liability	\$[**] dollar) per claim/ \$[**] dollar) annual aggregate	Coverage for all acts, errors, omissions, negligence, network security and privacy risks, including but not limited to unauthorized access, failure of security, breach of privacy perils, wrongful disclosure of data, disclosure of HIPAA / GDPR protected health information, collection, or other negligence in the handling of confidential information, privacy perils, and including coverage for related regulatory defense and penalties	Company
Workers Compensation	Statutory	Statutory	Both Parties
Commercial General Liability	\$[**] dollar) per occurrence/\$\$[**] dollar) annual aggregate	Coverage arising from premises, operations, products and completed operations, personal injury, advertising injury, bodily injury and property damage, including contractual liability	Both Parties
Umbrella Liability	\$[**] dollar) per occurrence and \$[**] dollar) annual aggregate	Coverage provides excess, follow-form coverage above all liability limits required herein	Both Parties

8.3. <u>LIMITATION OF CONSEQUENTIAL DAMAGES</u>. EXCEPT FOR (A) CLAIMS OF A THIRD PARTY THAT ARE SUBJECT TO INDEMNIFICATION UNDER THIS ARTICLE 8, (B) CLAIMS ARISING OUT OF A PARTY'S WILLFUL MISCONDUCT OR (C) A PARTY'S BREACH OF SECTIONS 4.5, 4.6 OR 4.7 OR ARTICLE 10, NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL OR OTHER INDIRECT DAMAGES, OR FOR LOST OR IMPUTED PROFITS OR

ROYALTIES, OR FOR PUNITIVE DAMAGES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE.

ARTICLE 9. TERM; TERMINATION

- 9.1. <u>Term; Expiration</u>. This Agreement is effective as of the Effective Date and, unless earlier terminated pursuant to the other provisions of this ARTICLE 9, will expire, in its entirety, upon the later of (such period, the "Term"):
 - 9.1.1. the expiration of the last to expire Royalty Term under this Agreement with respect to all Products in all countries; and
 - 9.1.2. the date that Vertex is no longer Developing or Commercializing any Profit Share Product in the Field in the Territory.

9.2. <u>Termination of the Agreement</u>.

- 9.2.1. **Vertex's Termination for Convenience**. Vertex may terminate this Agreement in its entirety for convenience by providing written notice of its intent to terminate to Company, in which case, such termination will be effective 90 days after Company's receipt of such written notice.
- 9.2.2. Termination for Material Breach. If either Party (the "Non-Breaching Party") believes that the other Party (the "Breaching Party") is in material breach of this Agreement, the Non-Breaching Party may deliver written notice of such material breach to the Breaching Party. If the breach is curable, the Breaching Party will have [**] following its receipt of such written notice to cure such breach (except to the extent such breach involves the failure to make a payment when due, which breach must be cured within [**] following its receipt of such written notice). If the Breaching Party fails to cure such breach within such [**] or [**] period, as applicable, or the breach is not subject to cure, (a) the Non-Breaching Party may terminate this Agreement by providing written notice to the Breaching Party, in which case, this Agreement will terminate on the date on which the Breaching Party receives such written notice or (b) if the Non-Breaching Party is Vertex, Vertex may elect to exercise the alternate remedy provisions set forth in Section 9.3; provided, however, that if (i) the relevant breach (A) does not involve the Breaching Party's failure to make a payment when due and (B) is curable, but not reasonably curable within [**], and (ii) the Breaching Party is making a *bona* fide effort to cure such breach, the Non-Breaching Party's right to terminate this Agreement or Vertex's right (as the Non-Breaching Party) to elect to

exercise the alternate remedy provisions set forth in Section 9.3 on account of such breach will be suspended for so long as the Breaching Party is continuing to make such *bona fide* effort to cure such breach and if such breach is successfully cured, the Non-Breaching Party will no longer have the right to terminate this Agreement or Vertex (as the Non-Breaching Party) will no longer have the right to elect to exercise the alternate remedy provisions set forth in Section 9.3 on account of such breach.

- 9.2.3. **Disputes Regarding Material Breach**. Notwithstanding the foregoing, if the Breaching Party in Section 9.2.2 disputes in good faith the existence, materiality, or failure to cure of any breach, and provides written notice to the Non-Breaching Party of such Dispute within the relevant cure period, then the Non-Breaching Party will not have the right to terminate this Agreement in accordance with Section 9.2.2, or (in the case of Vertex as the Non-Breaching Party) the right to exercise the alternative remedy provisions of Section 9.3, as applicable, unless and until the relevant Dispute has been resolved in accordance with Section 11.12. During the pendency of any such Dispute, the relevant cure period shall be tolled, all the terms of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.
- 9.2.4. **Termination for Insolvency**. If Company makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within [**] after the filing thereof (each, an "**Insolvency Event**"), Vertex may terminate this Agreement in its entirety by providing written notice of its intent to terminate this Agreement to Company, in which case, this Agreement will terminate on the date on which Company receives such written notice.
- 9.3. <u>Alternate Remedies to Termination</u>. Upon the occurrence of the events set forth in Section 9.2.2 giving rise to Vertex's right to elect to exercise the alternate remedy provisions of this Section 9.3, Vertex may elect such alternate remedy provisions by providing written notice of such election to Company, in which case, this Agreement will continue in full force and effect with the following modifications, each at Vertex's election:
 - 9.3.1. Company's right to participate in the JRC, JSC and any other committees, subcommittees or working groups established pursuant to this Agreement will terminate;
 - 9.3.2. Company's Profit Share Option shall terminate;
 - 9.3.3. if the Profit Share Option has been exercised by Company, then Company will be deemed to have exercised the Opt-Out right, effective as of the

- date of such Vertex election, and, for clarity, as of the date Vertex provides written notice of such election under this Section 9.3, all Profit Share Products shall be deemed Royalty Products; and
- 9.3.4. solely if the applicable material breach is [**], all future success payments under Section 5.3 and milestone payments under Section 5.4 will be reduced by [**]% and royalty payments under Section 5.5 will be reduced by [**]% (after giving effect to all other applicable deductions under Section 5.5).

9.4. <u>Consequences of Expiration or Termination of the Agreement.</u>

- 9.4.1. **In General**. If this Agreement expires or is terminated by a Party pursuant to this ARTICLE 9, the following terms will apply to this Agreement:
 - (a) each Party will take all action required under Section 10.3 if requested by the other Party;
 - (b) termination or expiration of this Agreement for any reason will be without prejudice to any rights or financial compensation that will have accrued to the benefit of a Party prior to such expiration or termination. Such expiration or termination will not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement; and
 - (c) the following provisions of this Agreement will survive the expiration or termination of this Agreement: (i) Article 1 (to the extent necessary to construe the other surviving provisions); (ii) Sections 2.1.4 (last sentence only and solely with respect to any amounts accrued prior to expiration or termination), 2.1.8 (until the [**] anniversary of the effective date of expiration or termination), 2.1.10 (excluding the first sentence and, for clarity, expiration or termination shall be deemed to be "completion of the activities for which the applicable Materials were supplied" as referred to in the last sentence), 2.3.2, 4.1.1(c), 4.2.1(b), 4.3.3 (solely with respect to any amounts accrued prior to expiration or termination), 4.4, 5.1, 5.3 and 5.4 (solely with respect to any amounts accrued prior to expiration or termination), 5.5 (solely with respect to any amounts accrued prior to expiration or termination), 5.6, 5.7.3 (solely with respect to any amounts accrued prior to expiration or termination), 5.8 (solely with respect to any amounts accrued prior to expiration or termination), 5.9.3 (solely with respect to any amounts accrued prior to expiration or termination), 5.9.6 through 5.9.9 (inclusive, solely with respect to any amounts accrued prior to expiration or termination), 5.10 (solely with respect to any amounts accrued prior to expiration or termination), 5.11, 5.12 (solely for the period(s) set forth therein), 6.1, 6.2.3, 6.2.5, 6.3 (with respect to any Third Party

Infringement Claim commenced prior to expiration or termination or that results from or arises out of any research, development, manufacture or commercialization of any Licensed Agent or Product by or on behalf of Vertex or any of its Affiliates or Sublicensees prior to expiration or termination), 6.5 (provided that the phrase "that is not Competitive Infringement" shall be deleted such that the provision applies to any infringement and not only infringement that is not Competitive Infringement), 6.7 (solely with respect to Joint Agreement Patents), 6.10 (solely with respect to Joint Agreement Patents), 7.5, 8.1, 8.2 (for the period set forth therein), 8.3, 9.4, 10.1 (for the period set forth therein), 10.2 and 10.4 (for the period set forth in Section 10.1), 10.3, 10.5, 10.6.1 (second sentence only), 11.1, and 11.3 through 11.20 (inclusive), and (iii) Annex I.

- 9.4.2. **Early Termination**. If this Agreement is terminated by a Party pursuant to Sections 9.2.1, 9.2.2 or 9.2.4, the following terms will apply:
 - (a) except as set forth in Sections 9.4.2(c) or 9.4.1(c), the licenses granted by either Party to the other Party or its Affiliates under this Agreement will terminate;
 - (b) except as set forth in this Section 9.4, Vertex and its Affiliates will have no further rights or obligations under this Agreement with respect to Products, and Company and its Affiliates will have no further rights or obligations under this Agreement with respect to Products;
 - (c) except in the event of termination by Vertex for any reason, any permitted Sublicense of Vertex will, at the relevant sublicensee's option, survive such termination on the condition that such sublicensee is not in material breach of any of its obligations under such Sublicense. In order to effect this provision, at the request of the sublicensee, Company will enter into a direct license with the sublicensee on terms that are substantially the same terms as the applicable terms of this Agreement; *provided* that Company will not be required to undertake obligations in addition to those required by this Agreement, and Company's rights under such direct license will be consistent with its rights under this Agreement, taking into account the scope of the license granted under such direct license.

ARTICLE 10. CONFIDENTIALITY

10.1. <u>Confidentiality</u>. During the Term and for [**] thereafter, each Party (the "Receiving Party") receiving any Confidential Information of the other Party (the "Disclosing Party") hereunder will: (a) keep the Disclosing Party's Confidential

Information confidential; (b) not publish, or allow to be published, and will not otherwise disclose, or permit the disclosure of, the Disclosing Party's Confidential Information; and (c) not use, or permit to be used, the Disclosing Party's Confidential Information for any purpose, except, in each case, to the extent expressly permitted under this Agreement (including, for clarity, to exercise any of its rights and perform any of its obligations hereunder) or otherwise agreed in writing. Without limiting the generality of the foregoing, to the extent that either Party provides the other Party any Confidential Information owned by any Third Party, the Receiving Party will handle such Confidential Information in accordance with the terms of this ARTICLE 10 applicable to a Receiving Party.

- 10.2. **Authorized Disclosure**. Notwithstanding Section 10.1, each Party may disclose the other Party's Confidential Information to the extent such disclosure is reasonably necessary to:
 - (a) following discussion and good faith efforts to seek agreement between the Parties of such disclosure through the IP Committee, file or prosecute patent applications as contemplated by this Agreement;
 - (b) subject to the remainder of this Section 10.2, prosecute or defend litigation;
 - (c) exercise its rights and perform its obligations hereunder; *provided* that such disclosure is covered by terms of confidentiality similar to those set forth herein (except with respect to the duration of such terms, which will be commercially reasonable under the circumstances);
 - (d) its advisors (including financial advisors, attorneys and accountants), actual or potential acquisition partners, financing sources, investors, underwriters, (sub)licensees or subcontractors on a need to know basis; *provided* that such disclosure is covered by terms of confidentiality similar to those set forth herein (except with respect to the duration of such terms, which will be commercially reasonable under the circumstances), which may include professional ethical obligations;
 - (e) exercise the rights granted to such Party or its Affiliates in Section 4.1.1(c) or Section 4.2.1(b), as applicable, including granting sublicenses;
 - (f) subject to the remainder of this Section 10.2, comply with Applicable Law; or
 - (g) include such Confidential Information in Regulatory Filings.

In addition to the foregoing, Vertex may disclose Company's Confidential Information to Third Parties in connection with the actual or potential Exploitation of Licensed Agents or Products; *provided* that such disclosure is covered by terms of confidentiality similar to those set forth herein.

If a Party deems it reasonably necessary to disclose Confidential Information belonging to the other Party pursuant to Sections 10.2(b) or 10.2(f), the disclosing Party will, to the extent possible, give reasonable advance notice of such disclosure to the other Party and take reasonable measures to ensure confidential treatment of such information.

- 10.3. Expiration or Termination of this Agreement. Following the expiration or termination of this Agreement, if requested by the Disclosing Party, the Receiving Party will, at the Receiving Party's election, return or destroy, all data, files, records and other materials containing or comprising the Disclosing Party's Confidential Information, except to the extent such Confidential Information is necessary or reasonably useful to conduct surviving obligations or exercise surviving rights. Notwithstanding the foregoing, (a) the Receiving Party will be permitted to retain one copy of such data, files, records, and other materials for archival and legal compliance purposes and (b) the Receiving Party will not be required to delete or destroy any electronic back-up tapes or other electronic back-up files that have been created solely by the Receiving Party's or its Affiliate's automatic or routine archiving and back-up procedures, to the extent created and retained in a manner consistent with its or their standard archiving and back-up procedures.
- 10.4. Applicable Law; SEC Filings and Other Disclosures. Either Party may disclose the terms of this Agreement or activities performed hereunder to the extent required to comply with Applicable Law, including the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory; provided that, to the extent such disclosure includes terms or information that have not previously been so disclosed, such Party will provide the other Party a reasonable opportunity to review such disclosure and reasonably consider the other Party's comments regarding confidential treatment sought for such disclosure. Notwithstanding anything to the contrary in this Agreement, Company shall not disclose any non-publicly available terms of this Agreement to [**] unless and until the Parties have mutually agreed in writing upon redactions to such terms.
- 10.5. **Residual Knowledge**. Notwithstanding any provision of this Agreement to the contrary, any use of Residual Knowledge made by a Receiving Party outside of the rights granted under this Agreement shall be deemed not to be a breach of this Agreement; *provided* that any such use is on an "as is, where is" basis, with all faults and all representations and warranties disclaimed and at the Receiving Party's sole risk. For clarity, no license under any Patent is granted pursuant to this Section 10.5.
- 10.6. **Public Announcements; Publications**.

- 10.6.1. **Announcements**. On a date to be determined by Vertex, the Parties will jointly issue a press release regarding the signing of this Agreement in a mutually agreed form. Except (a) as set forth in the preceding sentence and (b) as set forth in Section 10.4, neither Party will make any public announcement regarding this Agreement or activities hereunder without the prior written approval of the other Party. Notwithstanding the foregoing, subject to Section 10.6.2, Vertex may make scientific publications or public announcements concerning its Research, Development, Manufacture or Commercialization activities with respect to any Licensed Agent or Product under this Agreement without Company's prior written approval.
- 10.6.2. **Publications**. During the Term, Vertex will submit to Company for review any proposed academic, scientific and medical public presentation that contains Company's Confidential Information and is related to any Licensed Agent or Product or to any activities conducted pursuant to this Agreement. Vertex will submit written copies of such proposed publication or presentation to Company no later than [**] before submission for publication or presentation (or [**] in advance in the case of an abstract). Company will provide its comments with respect to such publications and presentations within [**] after its receipt of such written copy (or [**] in the case of an abstract). If requested by Company, Vertex will redact Company's Confidential Information from any such proposed publication or presentation. Vertex will comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication. Company will not publish, present or make any publication with respect to the Licensed Agents, Products or Licensed Technology specifically related to the Licensed Agents or Products.

10.7. <u>Vertex Information Rights</u>.

- 10.7.1. If Vertex determines in good faith that Company is an entity that is subject to financial consolidation with Vertex for the purposes of its quarterly and annual financial statements (or otherwise requires such information in order to comply with GAAP), Company will make available to Vertex:
 - (a) as soon as practicable, but in any event within [**] after the end of each [**] (i) an unaudited balance sheet as of the end of such [**], (ii) unaudited statements of income and cash flows for such [**], (iii) an unaudited statement of stockholders' equity for such period, and (iv) a detailed trial balance as of the end of such [**], all prepared in accordance with GAAP (except that such financial statements may (A) be subject to year-end audit adjustments and (B) not contain all notes thereto that may be required in accordance with

- GAAP) and thereafter will promptly provide such other information as Vertex may reasonably request;
- (b) as soon as practicable, but in any event within [**] after the end of each [**] (i) an audited balance sheet as of the end of such [**], (ii) audited statements of income and cash flows for such [**], (iii) an audited statement of stockholders' equity for such [**] and (iv) a detailed trial balance as of the end of such [**], together with related footnotes all prepared in accordance with GAAP and audited and certified by a nationally recognized independent public accounting firm;
- on or prior to [**], Company will perform a 409A analysis of the fair value of Company's stock as of [**] of such year as prepared by an independent valuation expert; and
- (d) any other information or agreements requested by Vertex and reasonably necessary for the purposes of its quarterly and annual financial statements.

ARTICLE 11. MISCELLANEOUS

11.1. **Assignment**. This Agreement will not be assignable by either Party to any Third Party without the written consent of the non-assigning Party. Notwithstanding the foregoing, either Party may assign this Agreement or its rights and obligations under this Agreement, without the consent of the other Party, to an Affiliate or to a Third Party that acquires all or substantially all of the business or assets of such Party to which this Agreement relates (whether by merger, reorganization, acquisition, sale or otherwise), and agrees in writing to be bound by the terms of this Agreement; *provided* that such Affiliate or Third Party maintains the rights and abilities to perform the obligations of the assigning Party under this Agreement. This Agreement will be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein will be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 11.1 will be void.

11.2. <u>Change of Control of Company</u>.

- 11.2.1. **Notification**. Company will notify Vertex in writing promptly (and in any event within [**]) following the execution of a definitive agreement by Company, its Affiliates or its equity holders that could reasonably be expected to result in a Change of Control of Company.
- 11.2.2. Effects of Change of Control of Company.

- (a) If during the Term Company undergoes a Change of Control, upon the effective date of such Change of Control:
 - (i) Vertex's obligation to provide Company with Research reports in accordance with Section 2.1.11 and Development reports in accordance with Section 2.2.2 will terminate:
 - (ii) Company's Profit Share Option shall terminate; and
 - (iii) Vertex will have the right to terminate the performance by Company and its Affiliates of all or less than all Other Company Activities and, to the extent requested by Vertex, Company shall negotiate in good faith, agree, and diligently conduct a wind down plan with respect to such terminated activities.
- (b) If during the Term Company undergoes a Change of Control to a Third Party that is a Competitor or an Affiliate of a Competitor, upon the effective date of such Change of Control, in addition to the consequences set forth in Section 11.2.2(a):
 - (i) Vertex will have the right to terminate the JSC; and
 - (ii) Vertex's obligation to provide Company with any Development Plans, any Commercialization Plans, or any updates thereto will terminate.
- 11.3. <u>Force Majeure</u>. Each Party will be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides written notice of the Force Majeure to the other Party. Such excuse will continue for so long as the condition constituting a Force Majeure continues, on the condition that the nonperforming Party continues to use Commercially Reasonable Efforts to resume performance of its obligations under this Agreement.
- 11.4. **Representation by Legal Counsel**. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, no presumption will exist or be implied against the Party that drafted such terms and provisions.
- 11.5. <u>Notices</u>. All written notices which are required or permitted hereunder will be in writing and sufficient if delivered personally or sent by nationally-recognized overnight courier, or through email to the applicable email address, addressed as follows:

If to Vertex:

Vertex Pharmaceuticals Incorporated Attn: Business Development 50 Northern Avenue Boston, Massachusetts 02210 Email: [**]

with a copy to:

Vertex Pharmaceuticals Incorporated Attn: Corporate Legal 50 Northern Avenue Boston, Massachusetts 02210 Email: [**]

Eman. [

If to Company:

Verve Therapeutics, Inc. Attn: Business Development 500 Technology Square Cambridge, MA 02139

Email: [**]

with a copy to:

WilmerHale Attn: Sarah Tegan Hogan 60 State Street Boston, MA 02109

Email: sarah.hogan@wilmerhale.com

or to such other address as the Party to whom written notice is to be given may have furnished to the other Party in writing in accordance herewith. In addition, each Party will deliver a courtesy copy to the other Party's Alliance Manager concurrently with such notice. Any such written notice will be deemed to have been given and received by the other Party: (a) when delivered if personally delivered; or (b) on receipt if sent by overnight courier or email.

- 11.6. **Amendment**. No amendment, modification or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each of Vertex and Company.
- 11.7. <u>Waiver</u>. No provision of this Agreement will be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either Party of any breach of any provision hereof by the other Party will not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

- 11.8. Severability. If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same will not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement will be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement will be construed as if such clause of portion thereof had never been contained in this Agreement, and there will be deemed substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by Applicable Law.
- 11.9. **Descriptive Headings**. The descriptive headings of this Agreement are for convenience only and will be of no force or effect in construing or interpreting any of the provisions of this Agreement.
- 11.10. **Export Control**. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America or other countries that may be imposed upon or related to Company or Vertex from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate Governmental Authority.
- 11.11. Governing Law. This Agreement, and all claims arising under or in connection therewith, will be governed by and interpreted in accordance with the substantive laws of The Commonwealth of Massachusetts, without regard to conflict of law principles thereof.
- 11.12. <u>Dispute Resolution</u>. Subject to Section 11.12.4 regarding the resolution of certain Patent and Know-How-related disputes, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a "**Dispute**"), it will be resolved pursuant to Sections 11.12.1, 11.12.2 and 11.12.3.
 - 11.12.1. **Escalation to Executive Officers**. Either Party may refer any Dispute to the Executive Officers of the Parties, who will confer in good faith on the resolution of the issue, by delivering written notice to the other Party.
 - 11.12.2. **Mediation** If the Executive Officers are unable to agree on the resolution of any such Dispute (other than any Dispute (a) arising from the JRC that is subject to the final decision-making authority of either Party pursuant to Section 3.1.4 or (b) designated in the definition of "Net Sales" for resolution by Baseball Arbitration) within [**] (or such other period of time as mutually agreed by the Executive Officers) after such Dispute was first referred to them, then either Party may refer the matter to confidential mediation administered by the American Arbitration Association

("AAA") under its Mediation Procedures (subject to this Section 11.12.2). Such mediation shall begin within [**] following the service of such mediation notice. If the Parties are unable to agree on a mediator within [**] after service of the mediation notice, a mediator shall be appointed by the AAA. The mediation session shall last for at least [**] before any Party has the option to withdraw from the process. The Parties may agree to continue the mediation process beyond [**], until there is a settlement agreement, or one Party or the mediator states that there is no reason to continue. The Parties agree to have personnel with appropriate decision-making authority participate in the mediation process, including being present throughout the mediation session(s). Any period of limitations that would otherwise expire between the reference of the Disputes to the Executive Officers of the Parties and the conclusion of the mediation shall be extended until [**] after the conclusion of mediation. If the Dispute is not resolved through mediation, then either Party may initiate an arbitration proceeding pursuant to the procedures set forth in Section 11.12.3 by delivering a demand for arbitration to the other Party.

- 11.12.3. **Arbitration**. A Party may refer any Dispute to arbitration only after the Parties have escalated the Dispute to the Executive Officers pursuant to Section 11.12.1 and attempted to mediate the Dispute pursuant to Section 11.12.2, which process shall be a condition precedent to arbitration. For clarity, no Dispute (x) arising from the JRC that is subject to the final decision-making authority of either Party pursuant to Section 3.1.4 or (y) designated in the definition of "Net Sales" for resolution by Baseball Arbitration will be subject to arbitration pursuant to this Section 11.12.3. Any Dispute referred to arbitration under this Section 11.12.3 shall be resolved using the following procedures:
 - (a) <u>Binding Arbitration</u>. Any Dispute referred to arbitration under this Section 11.12.3 will be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules (the "**Rules**") of the AAA by an arbitral tribunal composed of three impartial arbitrators, all of whom will have relevant experience in the pharmaceutical industry. Unless otherwise agreed by the Parties in writing, each of the Parties shall appoint one arbitrator within [**] after the submission of the demand for arbitration, and the third who will chair the arbitral tribunal shall be appointed by the two Party-appointed arbitrators within [**] after the appointment of the second arbitrator, or, failing agreement by the Party-appointed arbitrators, by the AAA in accordance with the Rules. If, at the time of the arbitration, the Parties agree in writing to submit the Dispute to a single arbitrator, said single arbitrator will (i) have relevant experience in the pharmaceutical industry and (ii) be appointed by agreement of the Parties within [**] after the demand for arbitration, or, failing such agreement, by the AAA in accordance with the Rules. In no case shall any candidate who participated in a prior

mediation or arbitration under this Agreement be appointed as an arbitrator for a Dispute unless explicitly agreed to by the Parties in writing. Unless otherwise agreed by the Parties hereto, all such arbitration proceedings will be held in Boston, MA, U.S.A. All arbitration proceedings will be conducted in the English language. The Dispute will not be subject to the Commercial Arbitration Rules' Expedited Procedures, regardless of the amount in controversy, unless otherwise agreed by the Parties in writing.

- (b) <u>Limited Discovery</u>. Documentary discovery may be conducted at the discretion of the arbitrator(s), provided that any such discovery will (i) be limited to documents that are relevant and material to the outcome of the dispute, (ii) be conducted pursuant to document discovery procedures as set forth under the International Bar Association Rules on the Taking of Evidence in International Arbitration, and (iii) be conducted subject to the schedule stipulated by the Parties, or in the absence of stipulation, the schedule ordered by the arbitrator(s). At the request of a Party, the arbitrator(s) may at their discretion order the deposition of witnesses only to the extent such witnesses have personal knowledge of facts that are relevant and material to the outcome of the dispute. Depositions shall be limited to a maximum of [**] depositions per Party, each of a maximum of [**] hours duration, unless the arbitrator(s) otherwise determine. Notwithstanding any provision of this Section 11.12.3 to the contrary, all discovery must be completed within [**] after the appointment of the arbitrator(s) or within such other period agreed by the Parties in writing.
- (c) Awards and Fees. The arbitrator(s) have the authority to make awards of declaratory relief and monetary damages, but they may not award damages excluded under Section 8.3, and will not under any circumstances have the authority or power to grant (i) equitable relief or (ii) orders for specific performance. Notwithstanding the foregoing, the arbitrator(s) do have the authority to order interim measures of protection during the arbitration to safeguard the arbitral process. The allocation of the costs of the arbitration, including reasonable attorney's fees, will be determined by the arbitrator(s), with the arbitrators having the option to have each side bear its own costs.
- (d) Rulings. All arbitration proceedings must be completed within [**] after the submission of the demand for arbitration under Section 11.12.2, except as the Parties may otherwise agree in writing. The Parties hereby agree that, subject to the provisions of this Section 11.12.3, the arbitrator(s) has authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrator(s) deem reasonable and necessary with or without petition therefor by

the Parties as well as the final award. The final award will be issued no more than [**] after the final submissions of the Parties, or as soon thereafter as practicable. All rulings by the arbitrator(s) will be final and binding on the Parties. The arbitrator(s) shall issue a reasoned decision that accompanies the final award.

- (e) <u>Enforcement of Rulings by Courts of Competent Jurisdiction</u>. Any ruling issued by the arbitrator(s) pursuant to Section 11.12.3(d) may be enforced in any court having jurisdiction over any of the Parties or any of their respective assets.
- (f) <u>Confidentiality</u>. All activities undertaken by the arbitrator(s) or the Parties pursuant to this Section 11.12.3 will be conducted subject to obligations of confidentiality no less restrictive than those set forth in ARTICLE 10. Further, the Parties acknowledge and agree that their respective conduct during the course of the arbitration, their respective statements and all information exchanged in connection with the arbitration, and the conduct of the arbitration and any information produced thereunder is Confidential Information under this Agreement and subject to the provisions of ARTICLE 10.
- 11.12.4. **Patent and Know-How Disputes**. Notwithstanding the foregoing in this Section 11.12, any claim regarding the ownership, interpretation, scope, validity, enforcement, enforceability, applicability or term of any Patent or the Creation of any Know-How, shall be brought by either Party in the federal courts located in Massachusetts, in each case, (a) unless the Parties agree in writing to submit such claim to arbitration pursuant to Sections 11.12.1, 11.12.2 and 11.12.3 or (b) except to the extent federal jurisdiction cannot be maintained, in which case such claim will be submitted to arbitration pursuant to Sections 11.12.1, 11.12.2 and 11.12.3.
- 11.12.5. **Equitable Relief**. Notwithstanding the foregoing in this Section 11.12, nothing contained in this Agreement will in any way limit or preclude a Party from, at any time, seeking or obtaining equitable relief hereunder, whether preliminary or permanent, including a temporary or permanent restraining order, preliminary or permanent injunction, specific performance or any other form of equitable relief, from any United States court of competent jurisdiction if necessary to protect the interests of such Party. Each Party agrees that its unauthorized release of the other Party's Confidential Information or its breach of Sections 4.5, 4.6 or 4.7 of this Agreement will cause irreparable damage to other Party for which recovery of damages would be inadequate, and that such other Party will be entitled to seek timely injunctive relief with respect to such breach, without the need to show irreparable harm or the inadequacy of monetary damages as a remedy, and without the requirement of having to post bond or other security, as well as any further relief that may be granted by a court of competent jurisdiction.

- 11.13. **Entire Agreement**. This Agreement constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties with respect to the subject matter hereof, including the CDA, which is hereby superseded and replaced in its entirety as of the Effective Date.
- 11.14. <u>Independent Contractors</u>. Subject to Annex I attached hereto, both Parties are independent contractors under this Agreement. Nothing contained herein will be deemed to create an employment, agency, joint venture or partnership relationship (other than for U.S. federal income tax purposes as provided in Section 11.15) between the Parties or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever. Each Party covenants hereunder to perform all tax compliance obligations and reporting consistent with the intent and provisions of this Section 11.14, Section 11.15 and Annex I.
- 11.15. <u>Tax Partnership</u>. Except as otherwise provided in, and subject to, Annex I attached hereto, the Parties agree not to treat the relationship between the Parties contemplated by this Agreement as giving rise to a partnership, joint venture, or other business entity for U.S. federal, state, local or non-U.S. income tax purposes, and the Parties shall not take any position, on a tax return or otherwise, inconsistent with this Section 11.15 and Annex I
- 11.16. <u>Transparency Laws</u>. Company agrees that Vertex may publicly disclose any information related to (a) this Agreement, (b) any payment or transfer of value made to Company by Vertex hereunder, or (c) any payment or transfer of value made by Company to any Third Party or Affiliate in connection with this Agreement, in each case (a)-(c), to the extent reasonably required by transparency industry regulations and transparency laws and by any means, including reporting through any government platform or system, Vertex's and its Affiliates' websites or any other platform or system. Company will promptly (and in any event within [**]) provide Vertex with any such information as reasonably requested by Vertex to enable compliance with transparency industry regulations and transparency laws.
- 11.17. <u>Interpretation</u>. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include," "includes" and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such

amendments, supplements or modifications set forth herein), (e) any reference herein to any Person will be construed to include the Person's successors and assigns, (f) the words "herein," "hereof" and "hereunder," and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Schedules or Exhibits will be construed to refer to Sections. Schedules or Exhibits of this Agreement, and references to this Agreement include all Schedules and Exhibits hereto, (h) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes, e-mail or otherwise (but excluding text messaging or instant messaging), (i) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (j) any action or occurrence deemed to be effective as of a particular date will be deemed to be effective as of 11:59 PM ET on such date. (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or" and (1) the designation of any amount hereunder as "non-refundable" or "non-creditable" is not intended, and shall not be construed, to prevent a Party from pursuing any claim for damages hereunder seeking a refund or credit with respect to such amount (or from being awarded any such damages).

- 11.18. **No Third Party Rights or Obligations**. No provision of this Agreement will be deemed or construed in any way to result in the creation of any rights or obligations in any Person not a Party to this Agreement.
- 11.19. **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 11.20. <u>Counterparts</u>. This Agreement may be executed in two counterparts, each of which will be an original and both of which will constitute together the same document. Counterparts may be signed and delivered by digital transmission (*e.g.*, .pdf), each of which will be binding when received by the applicable Party. The Parties may execute this Agreement by electronically transmitted signature and such electronically transmitted signature will be as effective as an original executed signature page.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their representatives thereunto duly authorized as of the Effective Date.

VERTEX PHARMACEUTICALS INCORPORATED

By: <u>/s/</u>	Reshma Kewalramani
Name:	Reshma Kewalramani
Title:	Chief Executive Officer and President
VERVE	THERAPEUTICS, INC.
By: <u>/s/</u>	Andrew Ashe
Name:	Andrew Ashe
Title:	President, Chief Operating Officer, General Counsel
And Sec	retary
	Signature Page to Strategic Collaboration and License Agreement

Annex I

Tax Appendix

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CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sekar Kathiresan, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Verve Therapeutics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2022	By:	/s/ Sekar Kathiresan	
		Sekar Kathiresan, M.D.	
		Chief Executive Officer	
		(Principal Executive Officer)	

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Allison Dorval, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Verve Therapeutics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2022	By:	/s/ Allison Dorval
		Allison Dorval
		Chief Financial Officer
		(Principal Financial Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Verve Therapeutics, Inc. (the "Company") for the period ending September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Sekar Kathiresan, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

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Date: November 7, 2022	By:	/s/ Sekar Kathiresan	
		Sekar Kathiresan, M.D.	
		Chief Executive Officer	
		(Principal Executive Officer)	

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Verve Therapeutics, Inc. (the "Company") for the period ending September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Allison Dorval, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 7, 2022	Ву:	/s/ Allison Dorval	
		Allison Dorval	
		Chief Financial Officer	
		(Principal Financial Officer)	
		,	