UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-40489

VERVE THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-4800132**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
201 Brookline Avenue, Suite 601 Boston, Massachusetts	**02215**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 603-0070

Securities registered pursuant to Section 12(b) of the Act:

Title of 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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 1, 2024, the registrant had 84,624,529 shares of common stock, 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,” “predict,” “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 timing, progress, design and conduct of our Heart-2 clinical trial, a Phase 1b clinical trial of VERVE-102, including statements regarding the timing of enrollment and the period during which data from such clinical trial is expected to become available, and our Heart-1 clinical trial, a Phase 1b clinical trial of VERVE-101, including statements regarding next steps for such trial;
- the initiation, timing, progress, design and results of our research and development programs, preclinical studies and clinical trials, including the timing of our submissions of investigational new drug applications and clinical trial applications to regulatory authorities, and the timing of initiation of our planned clinical trial of VERVE-201;
- 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 results from studies in non-human primates into clinical trials in 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, including our collaborations with Eli Lilly and Company and Vertex Pharmaceuticals Incorporated; and
- the potential impact of public health epidemics or pandemics and of global economic developments, including fluctuations in inflation and interest rates, on our business, operations, strategy and goals.

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 early in our development efforts and have not yet completed a clinical trial. 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;
- *In vivo* 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 our lead product candidates 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 and develop 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 and interim, preliminary or top-line data from our clinical trials may materially change as participant enrollment continues, more participant data become available and audit and verification procedures are conducted. As a result, interim, preliminary or top-line data from a clinical trial should be viewed with caution until the final data are available;
- If we experience delays or difficulties in the enrollment of patients in our clinical trials, our clinical trials could experience significant delays and our receipt of necessary regulatory approvals could be delayed or prevented;
- If any of the product candidates we develop, or the delivery modes we rely on to administer them, including lipid nanoparticles, cause serious adverse events, undesirable side effects or unexpected characteristics, such adverse events, side effects or characteristics could require us to abandon or limit development of the product candidates, delay or prevent regulatory approval of the product candidates, limit the commercial potential of our product candidates 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 demand for our potential products and increased regulatory scrutiny of genetic medicines may adversely affect our ability to obtain regulatory approvals for our product candidates;
- 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 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;
- 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. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. 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 licensing 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 and delivery, 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; and
- We face substantial competition, which may result in others discovering, developing or commercializing products before us or more successfully than we do. The market with respect to new products for the treatment of cardiovascular disease, for which the standard of care is well established, is particularly competitive.

Table of Contents

		Page
PART I.	FINANCIAL INFORMATION	1
Item 1.	Financial Statements (Unaudited)	1
	Condensed Consolidated Balance Sheets	1
	Condensed Consolidated Statements of Operations and Comprehensive Loss	2
	Condensed Consolidated Statements of Stockholders' Equity	3
	Condensed Consolidated Statements of Cash Flows	4
	Notes to Condensed Consolidated Financial Statements (Unaudited)	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	25
Item 4.	Controls and Procedures	25
PART II.	OTHER INFORMATION	27
Item 1.	Legal Proceedings	27
Item 1A.	Risk Factors	27
Item 2.	Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities	90
Item 5.	Other Information	90
Item 6.	Exhibits	91
Signatures		92

Part I — Financial Information

Item 1. Financial Statements

Verve Therapeutics, Inc.
Condensed consolidated balance sheets

(in thousands, except share and per share amounts) (unaudited)	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 141,490	$ 206,180
Marketable securities	434,458	417,770
Collaboration receivable	3,040	5,897
Prepaid expenses and other current assets	11,899	8,102
Total current assets	590,887	637,949
Property and equipment, net	20,195	22,505
Restricted cash	4,774	4,774
Operating lease right-of-use assets	81,736	85,295
Other long term assets	3,318	2,165
Total assets	$ 700,910	$ 752,688
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,833	$ 6,636
Accrued expenses	19,762	20,178
Deferred revenue, current	3,479	—
Lease liability, current	10,293	10,192
Total current liabilities	40,367	37,006
Long term lease liability	62,183	64,715
Success payment liability	971	2,720
Deferred revenue, non-current	51,153	48,556
Other long term liabilities	142	189
Total liabilities	154,816	153,186
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	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized, 84,552,269 and 81,969,693 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	85	82
Additional paid-in capital	1,189,470	1,143,453
Accumulated other comprehensive income (loss)	(615)	272
Accumulated deficit	(642,846)	(544,305)
Total stockholders' equity	546,094	599,502
Total liabilities and stockholders' equity	$ 700,910	$ 752,688

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

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

(in thousands, except share and per share amounts) (unaudited)	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Collaboration revenue	$ 6,692	$ 2,093	$ 12,387	$ 3,497
Operating expenses:				
Research and development	50,984	47,260	99,361	94,370
General and administrative	14,547	13,416	28,709	25,969
Total operating expenses	65,531	60,676	128,070	120,339
Loss from operations	(58,839)	(58,583)	(115,683)	(116,842)
Other income (expense):				
Change in fair value of success payment liability	1,671	(662)	1,749	76
Interest and other income, net	7,429	5,438	15,565	10,984
Total other income, net	9,100	4,776	17,314	11,060
Loss before provision for income taxes	(49,739)	(53,807)	(98,369)	(105,782)
Provision for income taxes	(66)	(176)	(172)	(176)
Net loss	$ (49,805)	$ (53,983)	$ (98,541)	$ (105,958)
Net loss per common share, basic and diluted	$ (0.59)	$ (0.87)	$ (1.18)	$ (1.71)
Weighted-average common shares used in net loss per share, basic and diluted	84,226,523	61,953,992	83,679,742	61,871,158
Comprehensive loss:				
Net loss	$ (49,805)	$ (53,983)	$ (98,541)	$ (105,958)
Other comprehensive loss:				
Unrealized loss on marketable securities	(115)	(517)	(887)	(60)
Comprehensive loss	$ (49,920)	$ (54,500)	$ (99,428)	$ (106,018)

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

Verve Therapeutics, Inc.
Condensed consolidated statements of stockholders' equity

(in thousands, except share amounts) (unaudited)	Common stock Shares	Common stock Amount	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2022	61,730,816	$ 62	$ 895,801	$ (694)	$ (344,237)	$ 550,932
Exercise of stock options	29,010	—	116	—	—	116
Issuance of common stock from At-the-Market offering, net of issuance costs of $126	103,184	—	1,922	—	—	1,922
Unrealized gain on marketable securities	—	—	—	457	—	457
Stock-based compensation	—	—	8,024	—	—	8,024
Net loss	—	—	—	—	(51,975)	(51,975)
Balance at March 31, 2023	61,863,010	62	905,863	(237)	(396,212)	509,476
Exercise of stock options	98,598	-	548	-	-	548
Vesting of restricted stock units	50,537	-	-	-	-	-
Issuance of common stock under employee stock purchase plan	52,134	-	685	-	-	685
Unrealized loss on marketable securities	-	-	-	(517)	-	(517)
Stock-based compensation	-	-	9,013	-	-	9,013
Net loss	-	-	-	-	(53,983)	(53,983)
Balance at June 30, 2023	62,064,279	62	916,109	(754)	(450,195)	465,222
Balance at December 31, 2023	81,969,693	$ 82	$ 1,143,453	$ 272	$ (544,305)	$ 599,502
Exercise of stock options	76,044	—	301	—	—	301
Vesting of restricted stock units	7,290	—	—	—	—	0
Issuance of common stock from At-the-Market offering, net of issuance costs of $747	1,766,835	2	22,431	—	—	22,433
Unrealized loss on marketable securities	—	—	—	(772)	—	(772)
Stock-based compensation	—	—	10,341	—	—	10,341
Net loss	—	—	—	—	(48,736)	(48,736)
Balance at March 31, 2024	83,819,862	84	1,176,526	(500)	(593,041)	583,069
Exercise of stock options	520,995	1	825	-	-	826
Vesting of restricted stock units	104,426	-	-	-	-	-
Issuance of common stock under employee stock purchase plan	106,986	-	472	-	-	472
Unrealized loss on marketable securities	-	-	-	(115)	-	(115)
Stock-based compensation	-	-	11,647	-	-	11,647
Net loss	-	-	-	-	(49,805)	(49,805)
Balance at June 30, 2024	84,552,269	$ 85	$ 1,189,470	$ (615)	$ (642,846)	$ 546,094

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

Verve Therapeutics, Inc.
Condensed consolidated statements of cash flows

(unaudited, in thousands)	Six months ended June 30, 2024	2023
Cash flows from operating activities:		
Net loss	$ (98,541)	$ (105,958)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	3,299	2,464
Non-cash lease expense	3,559	3,321
Net accretion of discount on marketable securities	(7,505)	(7,551)
Stock-based compensation	21,988	17,037
Change in fair value of success payments liabilities	(1,749)	(76)
Changes in operating assets and liabilities:		
Collaboration receivable	2,854	(1,081)
Prepaid expenses and other assets	(4,946)	(1,874)
Accounts payable	247	1,471
Accrued expenses and other liabilities	(90)	(549)
Operating lease liabilities	(2,432)	(4,262)
Deferred revenue	6,076	-
Net cash used in operating activities	(77,240)	(97,058)
Cash flows from investing activities:		
Purchases of property and equipment	(1,413)	(6,037)
Purchases of marketable securities	(276,098)	(246,877)
Maturities of marketable securities	266,029	301,331
Net cash (used in) provided by investing activities	(11,482)	48,417
Cash flows from financing activities:		
Proceeds from exercise of stock options	1,127	664
Proceeds from issuance of common stock, net of issuance costs	22,433	1,922
Issuance of common stock under employee stock purchase plan	472	685
Net cash provided by financing activities	24,032	3,271
Decrease in cash, cash equivalents and restricted cash	(64,690)	(45,370)
Cash, cash equivalents and restricted cash—beginning of period	210,954	120,236
Cash, cash equivalents and restricted cash—end of period	$ 146,264	$ 74,866
Supplemental disclosure of noncash investing and financing activities:		
Property and equipment additions included in accounts payable and accrued expenses	$ 511	$ 532

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 clinical-stage company developing a new class of genetic medicines for cardiovascular disease with the potential to transform 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.

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 $575.9 million as of June 30, 2024 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 marketing, distribution or 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 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 condensed consolidated financial statements contain all adjustments that are necessary to present fairly the Company’s financial position as of June 30, 2024, the results of its operations and other comprehensive loss for the three and six months ended June 30, 2024 and 2023, stockholders’ equity for the three and six months ended June 30, 2024 and 2023 and cash flows for the six months ended June 30, 2024 and 2023. Such adjustments are of a normal and recurring nature. The results for the three and six months ended June 30, 2024 are not necessarily indicative of the results for the year ending December 31, 2024, 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, 2023, and the notes thereto, included in the Company’s Annual Report on Form 10-K filed with the SEC on February 27, 2024.

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, 2023, and notes thereto, included in the Company's Annual Report on Form 10-K filed with the SEC on February 27, 2024. Since the date of those financial statements, there have been no 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 condensed consolidated balance sheet that sum to the total of the same amounts shown in the condensed consolidated statements of cash flows is as follows:

(in thousands)	June 30, 2024	June 30, 2023
Cash and cash equivalents	$ 141,490	$ 70,042
Restricted cash	4,774	4,824
Total cash, cash equivalents and restricted cash	$ 146,264	$ 74,866

3. Marketable securities

Marketable securities by security type consisted of the following:

	June 30, 2024			
(in thousands)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
U.S. treasury bills and notes	$ 192,906	$ 28	$ (313)	$ 192,621
U.S. agency securities	242,167	2	(332)	241,837
Total	$ 435,073	$ 30	$ (645)	$ 434,458

	December 31, 2023			
(in thousands)	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
U.S. treasury bills and notes	$ 147,978	$ 144	$ (15)	$ 148,107
U.S. agency securities	269,520	277	(134)	269,663
Total	$ 417,498	$ 421	$ (149)	$ 417,770

The remaining contractual maturities of all marketable securities were less than 15 months as of June 30, 2024 and 24 months as of December 31, 2023. The gross unrealized losses on the Company's marketable securities of $0.6 million and $0.1 million as of June 30, 2024 and December 31, 2023, respectively, were caused by interest rate increases which resulted in the decrease in market value of these securities. Because the decline in fair value is attributable to changes in interest rates and not credit quality, and because the Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be maturity, the Company did not consider those marketable securities to be impaired at June 30, 2024 or December 31, 2023. None of the Company's marketable securities have been in a continuous unrealized loss position for 12 months or greater as of June 30, 2024 or December 31, 2023.

4. Property and equipment, net

Property and equipment, net, consisted of the following:

(in thousands)	June 30, 2024	December 31, 2023
Lab equipment	$ 29,754	$ 28,851
Leasehold improvements	776	726
Furniture and fixtures	2,323	2,323
Computer equipment	997	997
Total property and equipment	33,850	32,897
Less accumulated depreciation	(13,655)	(10,392)
Property and equipment, net	$ 20,195	$ 22,505

The following table summarizes depreciation expense incurred:

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2024	2023	2024	2023
Depreciation expense	$ 1,667	$ 1,337	$ 3,299	$ 2,464

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 the Company's license agreement with the President and Fellows of Harvard College ("Harvard") and The Broad Institute, Inc. (“Broad”), which license agreement is referred to herein as the Harvard/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 June 30, 2024			
(in thousands)	Fair value	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 71,309	$ 71,309	$ —	$ —
Marketable securities:				
U.S. treasury bills and notes	192,621	—	192,621	—
U.S. agency securities	241,837	—	241,837	—
Total assets	$ 505,767	$ 71,309	$ 434,458	$ —
Liabilities				
Success payment liability	$ 971	$ —	$ —	$ 971
Total liabilities	$ 971	$ —	$ —	$ 971

	As of December 31, 2023			
(in thousands)	Fair value	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 120,987	$ 120,987	$ —	$ —
Marketable securities:				
U.S. treasury bills and notes	148,107	—	148,107	—
U.S. agency securities	269,663	—	269,663	—
Total assets	$ 538,757	$ 120,987	$ 417,770	$ —
Liabilities				
Success payment liability	$ 2,720	$ —	$ —	$ 2,720
Total liabilities	$ 2,720	$ —	$ —	$ 2,720

Cash Equivalents—Cash equivalents of $71.3 million and $121.0 million as of June 30, 2024 and December 31, 2023, 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.

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 mid ten-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.

The success payment liability is stated at fair value and is classified in Level 3 of the fair value hierarchy 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 remeasured the liability at fair value with decreases of $1.7 million in both the three and six months ended June 30, 2024, and an increase of $0.7 million recorded to other expense and a decrease of $0.1 million recorded to other income for the three and six months ended June 30, 2023, respectively.

The primary inputs used in valuing the success payment liability at June 30, 2024 and December 31, 2023, were as follows:

	At June 30, 2024	At December 31, 2023
Fair value of common stock (per share)	$ 4.88	$ 13.94
Equity volatility	90 %	83 %

The reconciliation of change in the fair value of financial instruments based on Level 3 inputs for the six months ended June 30, 2024 is as follows:

(in thousands)	Success payment liability
Balance at December 31, 2023	$ 2,720
Change in fair value	(1,749)
Balance at June 30, 2024	$ 971

The reconciliation of change in the fair value of financial instruments based on Level 3 inputs for the six months ended June 30, 2023 is as follows:

(in thousands)	Success payment liability
Balance at December 31, 2022	$ 2,885
Change in fair value	(76)
Balance at June 30, 2023	$ 2,809

6. Accrued expenses

Accrued expenses consisted of the following:

(in thousands)	June 30, 2024	December 31, 2023
Employee compensation and related benefits	$ 9,609	$ 12,342
Accrued external research and development expenses	6,527	4,856
Professional fees	2,752	1,492
License and milestone payments	310	500
Other	564	988
Total	$ 19,762	$ 20,178

7. Leases

The Company's operating lease activity is comprised of non-cancelable facility leases for office and laboratory space in 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 Topic 842, "Leases". The embedded leases are considered short term leases, as the contractual terms are 12 months or less. Accordingly, no lease liability or right-of-use asset has been recorded. The Company has recognized $0.2 million and $2.1 million of short term lease costs associated with the embedded leases during the three and six months ended June 30, 2024, respectively. The Company has recognized $0.3 million and $0.5 million of short term lease costs associated with the embedded leases during the three and six months ended June 30, 2023, respectively.

The components of operating lease cost were as follows:

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2024	2023	2024	2023
Operating lease costs	$ 3,234	$ 3,234	$ 6,468	$ 6,468
Variable lease costs	1,015	769	2,072	1,648
Total	$ 4,249	$ 4,003	$ 8,540	$ 8,116

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

	Six months ended June 30,	
(in thousands)	2024	2023
Cash paid for amounts included in the measurements of lease liabilities:		
Operating cash flows related to operating leases	$ 5,282	$ 7,416

As of June 30, 2024, 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 8.5 years.

Future minimum commitments under non-cancelable leases as of June 30, 2024 were as follows:

Years ending December 31,	Amount (in thousands)
Remainder of 2024	$ 5,307
2025	10,894
2026	11,210
2027	11,534
2028	11,868
Thereafter	49,881
Total lease payments	$ 100,694
Less: interest	(28,218)
Present value of operating lease liabilities	$ 72,476

8. License agreements

The Company's significant license agreements are disclosed in Note 8, "License agreements," to the audited consolidated financial statements for the year ended December 31, 2023, included in the Company's Annual Report on Form 10-K filed

with the SEC on February 27, 2024. Since the date of those financial statements, there have been no changes to its license agreements, except as noted below.

Harvard/Broad license agreement

In March 2019, the Company entered into the Harvard/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.

To the extent achieved, the Company is obligated to pay up to an aggregate of $23.1 million and $54.0 million in development and sales-based milestones, respectively, pursuant to the Harvard/Broad License Agreement. In the three months ended June 30, 2024, a development milestone was triggered and amounts due to Harvard and Broad totaled $0.2 million. These amounts remained payable as of June 30, 2024.

Beam license agreement

In April 2019, the Company and Beam Therapeutics Inc. ("Beam") entered into a collaboration and license agreement (the “Beam Agreement”), which was amended and restated in July 2022 when the Company entered into an Amended and Restated Collaboration and License Agreement with Beam (the “ARCLA”). In October 2023, Beam transferred certain of its rights under the ARCLA to Eli Lilly and Company ("Lilly").

A development milestone payment of $0.1 million under one of Beam's third-party agreements was triggered in the three months ended June 30, 2024. This amount remained payable as of June 30, 2024.

9. Collaboration and license agreements

The Company's significant collaboration and license agreements are disclosed in Note 9, "Collaboration and license agreements," to the audited consolidated financial statements for the year ended December 31, 2023 included in the Company’s Annual Report on Form 10-K filed with the SEC on February 27, 2024. Since the date of those financial statements, there have been no changes to its collaboration and license agreements, except as noted below.

Vertex agreement

In July 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.

During the three and six months ended June 30, 2024, the Company recognized $3.0 million and $6.0 million of revenue, respectively, associated with the Vertex Agreement related to research services performed during the periods. As of June 30, 2024, the Company has recorded $20.0 million as non-current deferred revenue. During the three and six months ended June 30, 2023, the Company recognized $2.1 million and $3.5 million of revenue, respectively, associated with the Vertex Agreement related to research services performed during the periods. 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 six months ended June 30, 2024 and 2023.

Lilly agreement

In June 2023, the Company entered into a Research and Collaboration Agreement (the “Lilly Agreement”) with Lilly for an exclusive, five-year worldwide research collaboration initially focused on advancing the Company’s discovery-stage *in vivo* gene editing lipoprotein(a) program. The Lilly Agreement became effective in July 2023.

During the three and six months ended June 30, 2024, the Company recognized $3.7 million and $6.4 million, respectively, of revenue associated with the Lilly Agreement related to the research and development activities under the Lilly Agreement (the "Lilly Research Services") performed during the periods, inclusive of the $0.2 million cumulative catch-up related to the $5.0 million research and development milestone achieved in March 2024. As of June 30, 2024, the Company has recorded $31.2 million of long-term deferred revenue and $3.5 million of short-term deferred revenue, of which $28.5 million related to the unexercised material rights and the remaining $6.2 million related to the Lilly Research Services and will be recognized over the period of service.

Costs incurred relating to the Company's collaboration programs under the Lilly 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 six months ended June 30, 2024.

10. Common stock

In July 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 its 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. During the three months ended June 30, 2024, the Company did not make any sales under the Sales Agreement. During the six months ended June 30, 2024, the Company sold 1,766,835 shares of its common stock under the Sales Agreement for aggregate net proceeds of $22.4 million, after deducting commissions and offering expenses payable by the Company. As of June 30, 2024, the Company has sold an aggregate of 4,547,688 shares of its common stock under the Sales Agreement for aggregate net proceeds of $86.0 million, after deducting commissions and offering expenses payable by the Company.

In July 2023, in connection with the execution of the Lilly Agreement, the Company and Lilly also entered into a stock purchase agreement with Lilly, pursuant to which the Company sold 1,552,795 shares of common stock to Lilly at a price of $19.32 per share, for an aggregate purchase price of $30.0 million.

In December 2023, the Company completed a follow-on public offering of common stock, pursuant to which the Company issued and sold 14,375,000 shares of its common stock, including 1,875,000 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 $10.00 per share. The Company received net proceeds of approximately $134.7 million after deducting underwriting discounts and offering expenses of approximately $9.0 million.

In December 2023, the Company also completed a private placement pursuant to a stock purchase agreement with Lilly for the sale and issuance of 2,296,317 shares of common stock at a purchase price of $10.00 per share for an aggregate purchase price of $23.0 million.

11. Stock-based compensation

The 2018 Equity Incentive Plan (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 (the "2021 Plan"), which became effective on June 16, 2021. The 2021 Plan provides for the grant of incentive stock options, nonstatutory 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. The shares reserved for issuance pursuant to the 2021 Plan are subject to an annual increase through January 1, 2031.

On January 1, 2024, 4,098,485 shares of the Company's common stock were added to the amount reserved for issuance under the 2021 Plan. As of June 30, 2024, the Company had reserved 14,242,655 shares of the Company's common stock for issuance of stock options, restricted stock, and restricted stock units, of which 2,939,799 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.

In February 2024, the board of directors adopted the 2024 Inducement Stock Incentive Plan (the "Inducement Plan"). The Inducement Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards to persons who (a) were not previously an employee or director or (b) are commencing employment with the Company following a bona fide period of non-employment, in either case, as an inducement material to such person's entry into employment with the Company and in accordance with the requirements of the Nasdaq Stock Market Rule 5635(c)(4). As of June 30, 2024, the Company had reserved 4,000,000 shares of the Company's common stock for issuance of nonstatutory stock options and restricted stock unit awards, of which 3,606,700 remained available for future grant under the Inducement Plan.

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

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	**2024**	**2023**	**2024**	**2023**
Research and development	$ 6,482	$ 4,848	$ 12,108	$ 9,337
General and administrative	5,165	4,165	9,880	7,700
Total stock-based compensation expense	$ 11,647	$ 9,013	$ 21,988	$ 17,037

Stock options

The following table provides a summary of stock option activity during the six months ended June 30, 2024:

	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, 2023	9,924,878	$ 16.98		
Granted	4,180,416	9.92		
Exercised	(597,039)	1.89		
Forfeited	(698,614)	19.81		
Outstanding at June 30, 2024	12,809,641	$ 15.22	7.9	$ 4,366
Exercisable at June 30, 2024	5,600,593	$ 15.43	6.5	$ 4,197
Expected to vest after June 30, 2024[1]	7,209,048	$ 15.06	9.0	$ 169

(1) This represents the number of unvested options outstanding as of June 30, 2024 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 June 30, 2024.

As of June 30, 2024, there was $72.1 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 2.6 years.

Restricted stock units

During the six months ended June 30, 2024, the Company granted 1,330,670 restricted stock units under the 2021 Plan and the Inducement 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 June 30, 2024 was as follows:

	Shares	Weighted-average grant date fair value per share
Unvested restricted stock units as of December 31, 2023	964,511	$ 19.92
Restricted stock units granted	1,330,670	$ 11.95
Restricted stock units vested	(111,716)	$ 25.08
Restricted stock units forfeited	(136,514)	$ 15.84
Unvested restricted stock units as of June 30, 2024	2,046,951	$ 14.73

As of June 30, 2024, there was $26.2 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 3.3 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 (the "ESPP"), as amended and restated, which became effective on June 16, 2021. The shares reserved for issuance pursuant to the ESPP are subject to an annual increase through January 1, 2031. On January 1, 2024, 819,697 shares of common stock were added to the amount reserved for sale under the ESPP. As of June 30, 2024, 1,989,903 shares remained available for issuance under the ESPP.

12. Net loss per share

The Company's potential dilutive securities, which include 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 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 for the period indicated because including them would have had an anti-dilutive effect:

	As of June 30,	
	2024	**2023**
Unvested restricted stock units	2,046,951	930,196
Outstanding options to purchase common stock	12,809,641	9,812,849
Total	14,856,592	10,743,045

13. Income taxes

The Company's effective income tax rate was de minimis for the three and six months ended June 30, 2024 and 2023. The income tax provision was $0.1 million and $0.2 million for the three and six months ended June 30, 2024, respectively. The income tax provision was $0.2 million for both the three and six months ended June 30, 2023. The provision for income taxes primarily relates to state income taxes based on gross interest income.

The effective income tax rate for the three and six months ended June 30, 2024 and 2023 differed from the 21% federal statutory rate primarily due to the valuation allowance maintained against the Company's net deferred tax assets.

14. Related party transactions

The board of directors of the Company elected an executive officer of Vertex to the Company's board of directors in June 2024. In July 2022, the Company and Vertex entered into the Vertex Agreement. During the three months ended June 30, 2024, the Company received reimbursements of $3.0 million, associated with the Vertex Agreement, which were recorded as revenue. See Note 9, "Collaboration and license agreements—Vertex Agreement".

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 February 27, 2024. 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 company developing a new class of genetic medicines for cardiovascular disease, or CVD, with the potential to transform 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. We are developing a pipeline of gene editing programs targeting the three lipoprotein pathways that drive atherosclerotic cardiovascular disease, or ASCVD, the most common form of CVD: low-density lipoprotein, or LDL, triglyceride-rich lipoproteins and lipoprotein(a), or Lp(a). Our lead programs target the *PCSK9* and *ANGPTL3* genes, which have been extensively validated as targets for lowering LDL cholesterol, or LDL-C. We believe that editing these genes could potently and durably lower LDL-C throughout the lifetimes of patients with or at risk for ASCVD.

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 in order to disrupt the production of proteins that can cause ASCVD. 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 our lead programs for the treatment of patients with familial hypercholesterolemia, or FH, an inherited 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 who continue to be impacted by high LDL-C levels. Ultimately, we believe that these treatments could potentially be developed for administration to people at risk for ASCVD as a preventative measure.

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 offerings, and our at-the-market, or ATM, equity offering program, and through our strategic collaborations with Vertex Pharmaceuticals Incorporated, or Vertex, and Eli Lilly and Company, or Lilly.

As of June 30, 2024, we had raised an aggregate of $1.1 billion in gross proceeds from sales of our preferred and common stock in private placements and common stock in public offerings.

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. Since our inception, we have incurred significant operating losses. Our net losses for the three and six months ended June 30, 2024 were $49.8 million and $98.5 million, respectively. As of June 30, 2024, we had an accumulated deficit of $642.8 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 conduct our ongoing Heart-2 Phase 1b clinical trial of VERVE-102, our product candidate targeting *PCSK9*, and initiate our planned clinical trial for VERVE-201, our product candidate targeting *ANGPTL3*, each of which utilizes our proprietary GalNAc-LNP delivery technology; determine the next steps for our Heart-1 Phase 1b clinical trial of VERVE-101; further develop base editing and novel gene editing technology, delivery technology and manufacturing capabilities; seek to discover and develop additional product candidates; 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, strategic alliances and marketing, distribution 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 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.

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 June 30, 2024, we had cash, cash equivalents and marketable securities of $575.9 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 late 2026. 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.”

Clinical and development programs

PCSK9 Program

VERVE-101 and VERVE-102, our product candidates targeting *PCSK9*, are 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 and VERVE-102 utilize 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 and VERVE-102 use the same base editor and guide RNA for *PCSK9*; however, VERVE-102 is delivered using a different, proprietary GalNAc-LNP delivery technology which is designed to allow the LNP to access liver cells using either the asialoglycoprotein receptor, or ASGPR, or the LDLR, whereas VERVE-101's LNP is designed to access liver cells using the LDLR.

Heart-2 clinical trial

VERVE-102 is being evaluated in the Heart-2 trial, an open-label Phase 1b clinical trial designed to evaluate the safety and tolerability of VERVE-102 in adult patients with heterozygous familial hypercholesterolemia, or HeFH, and/or premature coronary artery disease, or CAD, who require additional lowering of LDL-C, with additional analyses for pharmacokinetics and changes in blood PCSK9 protein and LDL-C levels. The trial is a single-ascending dose study that has an adaptive design.

We recently received clearance of our clinical trial application for VERVE-102 in Australia. Following earlier receipt of regulatory clearances in the United Kingdom and Canada, we initiated the Heart-2 trial with VERVE-102 in patients with HeFH and/or premature CAD in the second quarter of 2024. We expect to provide initial data from the Heart-2 trial and an update on the PCSK9 program in the first half of 2025 and plan to initiate a Phase 2 clinical trial for the PCSK9 program in the second half of 2025.

Heart-1 clinical trial

VERVE-101 is being evaluated in the Heart-1 trial, an open-label Phase 1b clinical trial with trial endpoints of safety and tolerability as well as changes in blood PCSK9 protein and LDL-C levels in patients living with HeFH, established ASCVD and uncontrolled hypercholesterolemia. A total of 13 participants have been dosed in the trial in New Zealand and the United Kingdom.

In April 2024, we announced that we had paused enrollment in the Heart-1 trial following the observation of transient asymptomatic laboratory abnormalities--a Grade 3 drug-induced transient increase in serum alanine aminotransferase as well as a serious adverse event of Grade 3 drug-induced thrombocytopenia--in the thirteenth patient dosed in the trial.

Enrollment remains paused in the Heart-1 trial as we complete our investigation of the observed laboratory abnormalities and further explore potential mitigation measures. Preliminary data from our investigations, including data from animal models, support our initial understanding that laboratory abnormalities observed in the Heart-1 trial are attributable to the LNP used in VERVE-101. We are continuing to work with regulatory authorities to define a path forward for VERVE-101. The safety events were previously reported to the U.S. Food and Drug Administration, the U.K. Medicines and Healthcare products Regulatory Agency, and the New Zealand Medicines and Medical Devices Safety Authority. The VERVE-101 investigational new drug application and other clinical trial applications remain active.

VERVE-201

VERVE-201, our product 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 ASCVD patients with refractory hypercholesterolemia, who have high LDL-C despite treatment with maximally tolerated standard of care therapies, as well as patients with homozygous familial hypercholesterolemia, or HoFH, a rare and often fatal inherited subtype of premature ASCVD characterized by extremely high blood LDL-C.

For VERVE-201, we are utilizing our internally developed GalNAc-LNP technology 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 ASGPR in the liver, thereby enabling uptake into the liver in HoFH patients. We have completed preclinical studies to support regulatory submissions for clinical development of VERVE-201 and expect to initiate a Phase 1b clinical trial with VERVE-201 in the second half of 2024, subject to regulatory clearances.

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 six months ended June 30, 2024, we recognized $6.7 million and $12.4 million, respectively, in collaboration revenue under a Strategic Collaboration and License Agreement, or the Vertex Agreement, and a Research and Collaboration Agreement, or the Lilly Agreement. We expect revenue related to these collaborations to increase as efforts under the collaborations continue. 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 successful and result in regulatory approval or we successfully enter into license or collaboration agreements with third parties, in addition to the Vertex Agreement and Lilly 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 efforts and preclinical and clinical development of our research programs, including under agreements with third parties, such as consultants, contractors and contract research organizations, or 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 and costs of third-party contract manufacturing organizations, or CMOs;
- the cost of laboratory supplies and research materials;
- costs incurred related to the research pursuant to the Vertex Agreement and the Lilly Agreement; 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, and as we continue to: (i) develop additional product candidates; (ii) build our manufacturing capabilities; and (iii) 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 investigational new drug applications 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, planned 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 public health epidemics.

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 success payment liability

We are obligated to pay to Harvard and Broad tiered success payments in the event our average market capitalization exceeds specified thresholds ascending from a mid ten-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 remaining potential aggregate success payments that could be payable by us are $25.0 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 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.

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

The provision for income taxes was $0.1 million and $0.2 million for the three and six months ended June 30, 2024, respectively. The provision for income taxes was $0.2 million for both the three and six months ended June 30, 2023. The provision for income taxes primarily relates to state income taxes based on gross interest income.

Results of operations

Comparison of three months ended June 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended June 30, 2024 and 2023:

	Three months ended June 30,		
(in thousands)	**2024**	**2023**	**Change**
Collaboration revenue	$ 6,692	$ 2,093	$ 4,599
Operating expenses:			
Research and development	50,984	47,260	3,724
General and administrative	14,547	13,416	1,131
Total operating expenses	65,531	60,676	4,855
Loss from operations	(58,839)	(58,583)	(256)
Other income (expense):			
Change in fair value of success payment liability	1,671	(662)	2,333
Interest and other income, net	7,429	5,438	1,991
Total other income, net	9,100	4,776	4,324
Loss before provision for income taxes	(49,739)	(53,807)	4,068
Provision for income taxes	(66)	(176)	110
Net loss	$ (49,805)	$ (53,983)	$ 4,178

Collaboration revenue

Collaboration revenue was $6.7 million and $2.1 million for the three months ended June 30, 2024 and 2023, respectively. During the three months ended June 30, 2024, collaboration revenue included $3.0 million related to research services from the Vertex Agreement and $3.7 million related to research services from the Lilly Agreement. During the three months ended June 30, 2023, collaboration revenue included $2.1 million related to research services from the Vertex Agreement. The increase in collaboration revenue in the three months ended June 30, 2024 was largely a result of the efforts related to the Lilly Agreement which commenced in July 2023.

Research and development expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2024 and 2023:

	Three months ended June 30,		
(in thousands)	**2024**	**2023**	**Change**
Employee-related expenses	$ 22,594	$ 17,210	$ 5,384
Raw material costs and external expenses associated with manufacturing activities, including third-party CMOs	7,959	12,193	(4,234)
Facility-related costs (including depreciation)	5,250	4,565	685
Lab supplies	4,665	4,768	(103)
Clinical trial costs	3,997	757	3,240
External expenses associated with preclinical studies performed by outside consultants, including third-party CROs	3,691	5,723	(2,032)
Other research and development costs	2,828	2,044	784
Total research and development expenses	$ 50,984	$ 47,260	$ 3,724

Research and development expenses were $51.0 million for the three months ended June 30, 2024, compared to $47.3 million for the three months ended June 30, 2023. The increase of $3.7 million was primarily due to the following:

- an increase of $5.4 million in employee-related expenses, including an increase of $1.6 million in stock-based compensation expense, driven by an increase in headcount of employees involved in research and development activities and expenses in connection with the separation of our former Chief Scientific Officer from our company in June 2024;
- an increase of $3.2 million in clinical trial costs associated with our ongoing Heart-2 clinical trial and costs associated with preparations for the initiation of our planned clinical trial for VERVE-201;
- an increase of $0.8 million in other research and development costs, primarily due to an increase in software subscriptions and other IT related costs; and

- an increase of $0.7 million in facility-related costs (including depreciation) and other allocated miscellaneous expenses.

These increases were partially offset by the following:

- a decrease of $4.2 million 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 trials;
- a decrease of $2.0 million in external expenses associated with preclinical studies (primarily animal-study costs) performed by outside consultants, including third-party CROs; and
- a decrease of $0.1 million in lab supplies.

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 including those under our collaborations, build our manufacturing capabilities and develop our gene editing and LNP delivery technology.

General and administrative expenses

General and administrative expenses were $14.5 million for the three months ended June 30, 2024, compared to $13.4 million for the three months ended June 30, 2023. The increase of $1.1 million was primarily attributable to the following:

- an increase of $1.2 million in employee-related expenses, including an increase of $1.0 million in stock-based compensation expense, driven by an increase in headcount to support our growth; partially offset by
- a decrease of $0.1 million in professional service fees.

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

Other income

Change in fair value of success payment liability

During the three months ended June 30, 2024, the change in fair value of the success payment liability was primarily due to the decrease in the fair value of our common stock, which resulted in a fair value adjustment of $1.7 million recorded as other income. During the three months ended June 30, 2023, the change in fair value of the success payment liability was primarily due to the increase in the fair value of our common stock, which resulted in a fair value adjustment of $0.7 million recorded as other expense.

Interest and other income, net

The increase of $2.0 million in interest and other income, net for the three months ended June 30, 2024 compared to the three months ended June 30, 2023 was primarily attributable to higher marketable securities balances and increased interest rates.

Comparison of six months ended June 30, 2024 and 2023

The following table summarizes our results of operations for the six months ended June 30, 2024 and 2023:

	Six months ended June 30,		
(in thousands)	**2024**	**2023**	**Change**
Collaboration revenue	$ 12,387	$ 3,497	$ 8,890
Operating expenses:			
Research and development	99,361	94,370	4,991
General and administrative	28,709	25,969	2,740
Total operating expenses	128,070	120,339	7,731
Loss from operations	(115,683)	(116,842)	1,159
Other income:			
Change in fair value of success payment liability	1,749	76	1,673
Interest and other income, net	15,565	10,984	4,581
Total other income, net	17,314	11,060	6,254
Loss before provision for income taxes	(98,369)	(105,782)	7,413
Provision for income taxes	(172)	(176)	4
Net loss	$ (98,541)	$ (105,958)	$ 7,417

Collaboration Revenue

Collaboration revenue was $12.4 million and $3.5 million for the six months ended June 30, 2024 and 2023, respectively. During the six months ended June 30, 2024, collaboration revenue included $6.0 million related to research services from the Vertex Agreement and $6.4 million related to the research services from the Lilly Agreement. During the six months ended June 30, 2023, collaboration revenue included $3.5 million related to research services and from the Vertex Agreement. The increase in collaboration revenue in the six months ended June 30, 2024 was largely a result of the efforts related to the Lilly Agreement which commenced in July 2023.

Research and development expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2024 and 2023:

	Six months ended June 30,		
(in thousands)	**2024**	**2023**	**Change**
Employee-related expenses	$ 42,909	$ 33,453	$ 9,456
Raw material costs and external expenses associated with manufacturing activities, including third-party CMOs	18,355	22,746	(4,391)
Facility-related costs (including depreciation)	10,458	9,019	1,439
Lab supplies	9,069	9,647	(578)
Clinical trial costs	6,682	2,432	4,250
External expenses associated with preclinical studies performed by outside consulting services, including third-party CROs	6,356	13,440	(7,084)
Other research and development costs	5,532	3,633	1,899
Total research and development expenses	$ 99,361	$ 94,370	$ 4,991

Research and development expenses were $99.4 million for the six months ended June 30, 2024, compared to $94.4 million for the six months ended June 30, 2023. The increase of $5.0 million was primarily due to the following:

- an increase of $9.5 million in employee-related expenses, including an increase of $2.8 million in stock-based compensation expense, driven by an increase in headcount of employees involved in research and development activities and expenses in connection with the separation of our former Chief Scientific Officer from our company in June 2024;
- an increase of $4.3 million in clinical trial costs associated with our ongoing Heart-2 clinical trial and costs associated with preparations for the initiation of our planned clinical trial for VERVE-201;
- an increase of $1.9 million in other research and development costs, primarily due to an increase in software subscriptions and other IT related costs; and
- an increase of $1.4 million in facility-related costs (including depreciation) and other allocated miscellaneous expenses.

These increases were partially offset by the following:

- a decrease of $7.1 million in external expenses associated with preclinical studies (primarily animal-study costs) performed by outside consultants, including third-party CROs;
- a decrease of $4.4 million 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 trials; and
- a decrease of $0.6 million in lab supplies.

General and administrative expenses

General and administrative expenses were $28.7 million for the six months ended June 30, 2024, compared to $26.0 million for the six months ended June 30, 2023. The increase of $2.7 million was primarily attributable to the following:

- an increase of $2.5 million in employee-related expenses, including an increase of $2.2 million in stock-based compensation expense, driven by an increase in headcount to support our growth;
- an increase of $0.1 million in professional service fees; and
- an increase of $0.1 million in other general and administrative costs.

Other income

Change in fair value of success payment liability

During the six months ended June 30, 2024, the change in fair value of the success payment liability was primarily due to the decrease in the fair value of our common stock, which resulted in a fair value adjustment of $1.7 million recorded as other income. During the six months ended June 30, 2023, the change in fair value of the success payment liability was primarily due to the decrease in the fair value of our common stock, which resulted in a fair value adjustment of $0.1 million recorded to other income.

Interest and other income, net

The increase of $4.6 million in interest and other income, net for the six months ended June 30, 2024 compared to the six months ended June 30, 2023 was primarily attributable to higher marketable securities balances and increased 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 clinical development of our programs. To date, we have funded our operations primarily through equity offerings and through our strategic collaborations and related private placements. Through June 30, 2024, we had raised an aggregate of $1.1 billion 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 offerings, and our ATM equity offering program. As of June 30, 2024, we had $575.9 million in cash, cash equivalents and marketable securities.

In addition to our existing cash, cash equivalents and marketable securities, we are eligible to earn milestone and other payments under our collaboration agreements with Lilly and Vertex. During the six months ended June 30, 2024, we received $5.0 million from Lilly due to the achievement of a research and development milestone under the Lilly Agreement. Our ability to earn the other milestone or other payments under our collaboration agreements and the timing of earning these amounts are dependent upon the timing and outcome of our development, regulatory and commercial activities and, as such, are uncertain at this time.

In July 2023, we sold and issued 1,552,795 shares of our common stock to Lilly in a private placement at a price of $19.32 per share for an aggregate purchase price of $30.0 million.

In August 2023, we received $30.0 million as an upfront payment from Lilly pursuant to the Lilly Agreement.

In December 2023, we issued and sold 14,375,000 shares of our common stock, including 1,875,000 shares of common stock sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $10.00 per share. We received net proceeds of approximately $134.7 million after deducting underwriting discounts and offering expenses of approximately $9.0 million.

In December 2023, in a private placement concurrent with the December 2023 underwritten offering, we issued and sold 2,296,317 shares of our common stock to Lilly at a price of $10.00 per share for an aggregate purchase price of $23.0 million.

In July 2022, we entered into the Open Market Sale Agreement, or the Sales Agreement, with Jefferies LLC, or Jefferies, as agent, pursuant to which we are entitled to offer and sell, from time to time at prevailing market rates, shares of our common stock, with an aggregate offering price of up to $200.0 million. 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. During the three months ended June 30, 2024, we did not make any sales under the Sales Agreement. During the six months ended June 30, 2024, we sold 1,766,835 shares of our common stock under the Sales Agreement for aggregate net proceeds of $22.4 million, after deducting commissions and offering expenses payable by us. As of June 30, 2024, we have sold an aggregate of 4,547,688 shares of common stock under the Sales Agreement for aggregate net proceeds of $86.0 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:

	Six months ended June 30,	
(in thousands)	**2024**	**2023**
Net cash used in operating activities	$ (77,240)	$ (97,058)
Net cash (used in) provided by investing activities	(11,482)	48,417
Net cash provided by financing activities	24,032	3,271
Decrease in cash, cash equivalents and restricted cash	$ (64,690)	$ (45,370)

Operating activities

For the six months ended June 30, 2024, net cash used in operating activities was $77.2 million, consisting primarily of our net loss of $98.5 million adjusted for non-cash items including $1.7 million associated with the fair value change in success payment liability and $7.5 million associated with the amortization of investment premiums, offset by stock-based compensation of $22.0 million, depreciation expense of $3.3 million, non-cash lease expense of $3.6 million, and a net increase in changes in our operating assets and liabilities of $1.7 million.

For the six months ended June 30, 2023, net cash used in operating activities was $97.1 million, consisting primarily of our net loss of $106.0 million, adjusted for non-cash items including $7.6 million associated with the non-cash accretion of discounts on our marketable securities, $0.1 million associated with the fair value change in success payment liability, and net changes in our operating assets and liabilities of approximately $6.2 million. These amounts were partially offset by non-cash expenses including stock-based compensation of $17.0 million, depreciation expense of $2.5 million, and non-cash lease expense of $3.3 million.

Investing activities

For the six months ended June 30, 2024, net cash used in investing activities was $11.5 million and consisted of purchases of marketable securities of $276.1 million and purchases of property and equipment of $1.4 million, primarily related to lab equipment, partially offset by maturities of marketable securities of $266.0 million.

For the six months ended June 30, 2023, net cash provided by investing activities was $48.4 million and consisted of maturities of marketable securities of $301.3 million, partially offset by purchases of marketable securities of approximately $246.9 million and purchases of property and equipment of $6.0 million, primarily related to lab equipment.

Financing activities

For the six months ended June 30, 2024, net cash provided by financing activities was $24.0 million, consisting primarily of net proceeds from the sale of our common stock through our ATM equity offering program of $22.4 million, proceeds from exercises of stock options of $1.1 million and proceeds from the issuance of shares through our employee stock purchase plan of $0.5 million.

For the six months ended June 30, 2023, net cash provided by financing activities was $3.3 million, consisting primarily of net proceeds from the sale of our common stock through our ATM equity offering program of $1.9 million, proceeds from exercises of stock options of $0.7 million and proceeds from the issuance of shares through our employee stock purchase plan of $0.7 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-2 Phase 1b clinical trial of VERVE-102;
- initiate our planned Phase 1b clinical trial of VERVE-201, subject to regulatory clearance;
- continue to evaluate the next steps for our Heart-1 Phase 1b clinical trial for VERVE-101;
- continue our current research programs and our preclinical development of product candidates;
- 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 Lilly 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 Lilly under our amended and restated collaboration and license agreement, milestone payments to Acuitas under our non-exclusive license agreement with Acuitas, milestone payments or success payments to Broad and Harvard under our license agreement with Broad and Harvard, and milestone payments to Novartis under our license agreement with Novartis, 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;
- further develop our base editing technology and develop 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-approval marketing requirements, such as a cardiovascular outcomes trial, which we expect will be required for VERVE-101 or VERVE-102 and VERVE-201;
- 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 June 30, 2024, we had cash, cash equivalents and marketable securities of $575.9 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 late 2026. 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 and six months ended June 30, 2024, 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 February 27, 2024. 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 and refer to Note 8, "License agreements," to the audited consolidated financial statements for the year ended December 31, 2023 included in our Annual Report on Form 10-K filed with the SEC on February 27, 2024 for more information on our potential payment obligations under our license agreements.

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.

During the three and six months ended June 30, 2024, there were no material changes to our critical accounting estimates from those described in our Annual Report on Form 10-K filed with the SEC on February 27, 2024.

Recently adopted accounting pronouncements

See Note 2, “Summary of significant accounting policies – Recently adopted accounting pronouncements” to our consolidated financial statements included in our Annual Report on Form 10-K filed with the SEC on February 27, 2024.

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 June 30, 2024, we had cash and cash equivalents of $141.5 million, which consisted of standard checking accounts and money market funds that invest primarily in U.S. government-backed securities and treasuries. In addition, as of June 30, 2024, we also had marketable securities of approximately $434.4 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

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 six months ended June 30, 2024.

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 June 30, 2024, 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

During the quarter ended June 30, 2024, we implemented a new enterprise resource planning system and new purchasing system for the purposes of maintaining our general ledger and reporting. There were no other 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 June 30, 2024 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.

From time to time, we may become involved in litigation or other legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

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 $98.5 million for the six months ended June 30, 2024 and $200.1 million for the year ended December 31, 2023. As of June 30, 2024, we had an accumulated deficit of $642.8 million. We have no approved products and we have not generated any revenue from product sales. 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 Strategic Collaboration and License Agreement, or the Vertex Agreement, with Vertex Pharmaceuticals Incorporated, or Vertex, in July 2022 and with the Research and Collaboration Agreement, or the Lilly Agreement, with Eli Lilly and Company, or Lilly, which became effective in July 2023.

We expect to continue to incur significant operating expenses and net 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-2 Phase 1b clinical trial of VERVE-102;
- initiate our planned Phase 1b clinical trial of VERVE-201, subject to regulatory clearance;
- continue to evaluate the next steps for our Heart-1 Phase 1b clinical trial for VERVE-101;
- continue our current research programs and our preclinical development of product candidates;
- 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 the Lilly 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 Lilly under our amended and restated collaboration and license agreement, or the ARCLA, 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;
- further develop our base editing technology and develop 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-approval marketing requirements, such as a cardiovascular outcomes trial, or CVOT, which we expect will be required for VERVE-101 or VERVE-102 and VERVE-201;
- establish commercial-scale current good manufacturing practices, or cGMP, capabilities through a third-party or our own manufacturing facility; and
- continue to operate as a public company.

In addition, our expenses will further 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 clinical trials or preclinical studies that are in addition to, or different than, those expected;
- there are any delays in completing our clinical trials or preclinical studies 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 initiated clinical development of our first product candidate in 2022 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.

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. We have not yet completed a clinical trial of any product candidate. 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 initiate and conduct clinical trials; continue research, development and preclinical testing; and potentially seek marketing approval for any of the 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 progress, costs and results of our ongoing Phase 1b clinical trial of VERVE-102 and planned Phase 1b clinical trial of VERVE-201, and if we determine to resume enrollment, our Phase 1b clinical trial of VERVE-101, and any future clinical development of such product candidates;
- the scope, progress, results and costs of discovery, preclinical and clinical development for any product candidates we may develop;
- the costs of developing or acquiring licenses for the delivery modalities that will be used with our future product candidates;
- 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-approval 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 collaboration or license agreements we enter into;
- 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 June 30, 2024, we had cash, cash equivalents and marketable securities of approximately $575.9 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 late 2026. 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, economic and other factors have recently caused significant disruption of global financial markets, which could continue and would reduce our ability to access capital, which could in the future negatively affect our liquidity. We have no committed source of additional capital or external funds 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 capital or 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, and conducting preclinical studies and clinical trials. We initiated our first clinical trial, a Phase 1b clinical trial for VERVE-101, in July 2022 and our second clinical trial, a Phase 1b clinical trial for VERVE-102, in the second quarter of 2024. We anticipate initiating our third clinical trial, a Phase 1b clinical trial for VERVE-201, in the second half of 2024, subject to regulatory clearances. Our other research programs 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 trials 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, 2023, we had federal NOL carryforwards of $188.2 million and state NOL carryforwards of $186.1 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 research and development tax 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 and research and development tax credit carryforwards 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 early in our clinical 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 early in our clinical development efforts and we have not yet completed a clinical trial of any product candidate. In April 2024, we announced that we had paused enrollment in the Heart-1 trial following the observation of transient asymptomatic laboratory abnormalities--a Grade 3 drug-induced transient increase in serum alanine aminotransferase, or ALT, and a serious adverse event of Grade 3 drug-induced thrombocytopenia--in the thirteenth patient dosed in the trial. We are conducting an investigation into the laboratory abnormalities and evaluating next steps for the Heart-1 trial. 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 investigational new drug, or IND, application and finalizing the trial design based on discussions with the FDA and other regulatory authorities. The FDA has in the past and may again in the future require us to complete additional preclinical studies and satisfy other requests for our clinical trials, causing the start or progress of such trials to be delayed. For example, in November 2022, the FDA placed our IND to conduct a clinical trial evaluating VERVE-101 in the United States on hold and requested

various information required to resolve the hold, including preclinical and clinical data. In October 2023, we announced that the FDA had lifted the clinical hold and cleared our IND. We have not activated clinical trial sites in the United States for VERVE-101 and cannot be certain that our IND for VERVE-101 will not be placed on clinical hold again in the future.

We also cannot be certain that regulatory authorities will permit us to initiate our planned clinical trial of VERVE-201 in the second half of 2024.

Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could determine that we have not satisfied their requirements to commence our clinical trials, 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 clinical trial applications in other countries, including in Canada, Australia, New Zealand and in countries in Europe.

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, the Medicines and Healthcare products Regulatory Agency, or the MHRA, and the EMA; manufacturing supply, capacity and expertise; a commercial organization; and significant marketing efforts. The success of VERVE-101, VERVE-102, 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 nonclinical and 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, planned 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.

In vivo 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 *in vivo* 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, VERVE-102 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. We cannot guarantee that progress or success in developing any particular product candidate based on gene editing technology will translate to other product candidates. Adverse developments in the clinical development efforts of other gene editing technology companies could also adversely affect our efforts or the perception of our product candidates by investors.

Similarly, other new gene editing technologies that have 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 novel gene editing development candidates as part of our collaborations with Vertex and Lilly, including seeking to identify and engineer specific gene editing systems and delivery systems directed to targets of interest. We may seek to develop novel gene editing technology for future programs. 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 targets under our agreements with Vertex and Lilly 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 have focused our research and development efforts for our lead product candidates 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 for our lead product candidates 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 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. Prime Medicine, Inc. and Beam Therapeutics Inc., or Beam, use 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 has initiated a Phase 3 trial of NTLA-2001, a CRISPR/Cas9-based gene editing product candidate for the treatment of hereditary transthyretin, or ATTR, amyloidosis with polyneuropathy and for the treatment of ATTR with cardiomyopathy. Chroma Medicine, Inc. and Tune Therapeutics, Inc. use epigenetic editing, designed to target genes and control chromatin conformation by coupling a DNA-binding domain with epigenetic effector domains. 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. 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.

Public health epidemics or pandemics 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, public health epidemics or pandemics may adversely impact economies worldwide, which could result in adverse effects on our business, operations and prospects.

Our business and operations could be adversely affected by public health epidemics or pandemics, including the recent COVID-19 pandemic, impacting the markets and industries in which we and our collaborators operate. We and our contract manufacturing organizations, or CMOs, and contract research organizations, or CROs, had experienced a reduction in the capacity to undertake research-scale production and to execute some preclinical studies, and we have faced and may in the future 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 may be shortages.

We and our CROs and CMOs may in the future face manufacturing disruptions and disruptions related to 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.

Moreover, the Biden Administration ended the public health emergency declarations related to the COVID-19 pandemic in May 2023 and the FDA ended a number of COVID-related policies. The FDA has retained a number of COVID-related policies but with appropriate changes, as applicable. It is unclear how, if at all, these policies will impact our efforts to develop and commercialize our product candidates.

We may in the future face impediments or delays to regulatory meetings and approvals due to any pandemic measures. We cannot be certain what the overall impact of such pandemics will be on our business, although for the reasons described above such pandemics have 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 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 to conduct a clinical trial evaluating VERVE-101 in the United States on hold and requested various information required to resolve the hold, including preclinical and clinical data. In October 2023, we announced that the FDA had lifted the clinical hold and cleared our IND for VERVE-101.

Furthermore, product candidates are subject to continued nonclinical 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. For example, in April 2024, we announced that we had paused enrollment in the Heart-1 trial following the observation of transient asymptomatic laboratory abnormalities--a Grade 3 drug-induced transient increase in ALT as well as a serious adverse event of Grade 3 drug-induced thrombocytopenia--in the thirteenth patient dosed in the trial. We are conducting an investigation into the laboratory abnormalities and evaluating next steps for the Heart-1 trial.

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.

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 initiated and begun conducting clinical trials starting in 2022. As a result, our belief in the potential capabilities of our programs is primarily based on 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 or nonclinical testing may produce results based on which we may decide, or regulators may require us, to conduct additional preclinical or nonclinical 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. For example, in consultation with our independent data and safety monitoring board for our Heart-1 trial, we paused enrollment in the Heart-1 trial following the observation of transient asymptomatic laboratory abnormalities--a Grade 3 drug-induced transient increase in ALT as well as a serious adverse event of Grade 3 drug-induced thrombocytopenia--in the thirteenth patient dosed in the trial. Regulatory 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.

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 collaborators 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. 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 or VERVE-102 for the treatment of patients with established ASCVD, the number of patients that may be required for clinical trials in order to obtain regulatory approval for that indication could be very high, and we may not be able to enroll a sufficient number of patients and as a result we may not be able to initiate or complete clinical trials of VERVE-101 or VERVE-102 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 VERVE-201 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 long-term 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.

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, 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.

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 develop, or the delivery modes we rely on to administer them, cause serious adverse events, undesirable side effects or unexpected characteristics, such adverse 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 are early in our development efforts and have not yet completed a clinical trial. There have been only a limited number of clinical trials involving the use of gene editing technologies and there are no completed clinical trials involving base editing technology similar to the gene editing technology we are using in VERVE-101, VERVE-102 and VERVE-201. Furthermore, there has not been any *in vivo* 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 trials, and the lack of observed side effects in preclinical studies does not guarantee that such side effects will not occur in human clinical trials. 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 and we believe that the observed laboratory abnormalities in the Heart-1 trial that were reported in April 2024 were attributable to the LNP delivery technology used in VERVE-101. 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 clinical trials and would result in significant delays in our programs.

Our proprietary GalNAc-LNPs, which we are utilizing in VERVE-102 and VERVE-201, are a novel delivery mechanism for delivery of gene editors to the liver and have not previously 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. For example, in April 2024, we announced that we had paused enrollment in the Heart-1 trial following the observation of transient asymptomatic laboratory abnormalities--a Grade 3 drug-induced transient increase in ALT as well as a serious adverse event of Grade 3 drug-induced thrombocytopenia--in the thirteenth patient dosed in the trial. We are conducting an investigation into the laboratory abnormalities and evaluating next steps for the Heart-1 trial.

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 demand for our potential products and increased regulatory scrutiny of genetic medicines may adversely affect our ability to obtain regulatory approval for our product candidates.

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 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 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, responses by the U.S., state or foreign governments to negative public perception or ethical concerns may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability.

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 products once approved. 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 our product candidates, 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, preliminary or top-line 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, preliminary or top-line results from our clinical trials. Interim results from clinical trials that we may complete, such as the interim data we reported from our Heart-1 trial of VERVE-101 in November 2023 and April 2024, 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. 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 have been conducting clinical trials, 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 have been conducting and plan to conduct additional clinical trials with one or more trial sites that are located outside the United States, including our Heart-1 trial of VERVE-101 which has been conducted at trial sites in New Zealand and the United Kingdom, and our Heart-2 trial of VERVE-102. We also plan to conduct our clinical trial of VERVE-201 at sites outside of the United States. Although the FDA may accept data from clinical trials conducted at sites outside the United States, acceptance of these data is subject to conditions imposed by the FDA. For example, where data from foreign clinical trial sites are not intended to serve as the sole basis for approval in the United States, the FDA will not accept the data as support for a marketing application unless the clinical trial was well designed and conducted in accordance with GCP requirements. The FDA must also be able to validate the data from the trial through an onsite inspection, if necessary. Where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of

recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, these clinical trials are subject to the applicable local laws of the jurisdictions where the trials are conducted. 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;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schema;
- foreign exchange fluctuations;
- diminished protection of intellectual property in some countries; and
- interruptions or delays resulting from geopolitical events, such as wars.

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 activities, 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 clinical trials, animal testing and research. Any of these third parties may terminate their engagements with us at any time or may face supply chain shortages or otherwise be unable to secure the requisite resources, such as animals used in our preclinical testing, to support our planned development activities. If we need to modify our development plans or 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 our 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, VERVE-102 and VERVE-201, 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 original collaboration and license agreement with Beam, or the Original 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 and under which Beam transferred certain of its rights and obligations to Lilly in October 2023; 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-102 and VERVE-201; 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; and in June 2023, we entered into the Lilly Agreement for a five-year worldwide research collaboration initially focused on advancing our discovery-stage *in vivo* gene editing lipoprotein(a) program. 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 ARCLA, 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 Original Beam Agreement, we issued 276,075 shares of our common stock to Beam; 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; and in connection with the effectiveness of the Lilly Agreement, we completed a private placement with Lilly pursuant to which we issued 1,552,795 shares of our common stock to Lilly. 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 mid ten-digit dollar amount to $10.0 billion, or in the event of a change of control 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. To date, we have paid success payments of approximately $6.3 million in cash under the Cas9 License Agreement.

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, as of June 2023, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the Unitary Patent Court, or the UPC. This is 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 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. 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 ARCLA, 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 may 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 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 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 a second interference (U.S. Interference No. 106,115) between 14 U.S. patent applications that are co-owned 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. In September 2022, the CVC appealed the PTAB's decision at the CAFC and the appeal is ongoing.

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.

The PTAB has currently suspended these subsequent interference proceedings with Toolgen and Sigma-Aldrich, pending the CAFC's decision of the appeal between the CVC and the Boston Licensing Parties over the outcome of the second interference.

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.

We or our licensors are subject to and may in the future become a party to similar proceedings or priority disputes in Europe or other foreign jurisdictions. For example, certain European patents that we have in-licensed from Broad were previously revoked in their entirety by the European Patent Office Opposition Division, or the Opposition Division. The Broad subsequently appealed and in March 2024, the Board of Appeals of the European Patent Office rendered a decision which overturned the prior revocations and remanded the cases back to the Opposition Division for further proceedings in connection with any remaining challenges. It is uncertain when or in what manner the Opposition Division will act on the remanded cases involving the in-licensed European patents.

There can be no assurance that the current appeal or these pending U.S. interference proceedings or the European proceedings will be ultimately resolved in favor of the Boston Licensing Parties. If the appeal in the second interference favors CVC, or 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 licensing 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 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 may expire when a 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 co-owners 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 and delivery, 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 *in vivo* gene editing technology, including base editing and delivery technology, is still new, and no such product candidates utilizing *in vivo* gene editing have been approved. 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 may 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. A finding of infringement may 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 regulatory 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 competing product.

In December 2022, Congress clarified through the Food and Drug Omnibus Reform Act that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the same first day on which such a product is approved as interchangeable with the reference product and the exclusivity period may be shared amongst multiple first interchangeable products. More recently, in October 2023, the FDA issued its first interchangeable exclusivity determination under the BPCIA.

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. Nonetheless, the approval of biosimilar products referencing any of our product candidates would have a material adverse impact on our business due to increased competition and pricing pressures. Moreover, there is a risk that any exclusivity we do receive 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. 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. The ultimate impact, implementation, and meaning of the BPCIA are subject to uncertainty, and any new regulations, guidance, policies or processes adopted by the FDA to implement the law could have a material adverse effect on the future commercial prospects for our biological products.

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 U.S. Supreme Court affirmed the Federal Circuit's holding 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 unpatentable subject matter, lack of novelty, obviousness, inadequate 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 unenforceability, we could 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 predominantly 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 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 products 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-102, 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 *PCSK9* 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 low density lipoprotein cholesterol, or 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 co-payments 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 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, which is a monoclonal antibody, or mAb, marketed as Repatha® by Amgen Inc., is approved by the FDA for the treatment of patients with heterozygous familial hypercholesterolemia, or HeFH, patients with HoFH and patients with ASCVD. Alirocumab, which is a mAb marketed as PRALUENT® by both 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. The approved mAb treatments act through extracellular inhibition of the PCSK9 protein. Inclisiran, which is a small interfering RNA, or siRNA, marketed as Leqvio® by Novartis, is approved in the United States for the treatment of patients with ASCVD, HeFH or elevated LDL-C who are at high risk of CVD 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 also aware of two orally administered small molecule product candidates that target the PCSK9 protein as a mechanism to lower LDL-C and reduce the risk of ASCVD in various stages of clinical development. These consist of MK-0616 from Merck & Co., Inc, for which Merck recently released data from a completed Phase 2b trial of adult patients with hypercholesterolemia and initiated a Phase 3 pivotal trial of adult patients with hypercholesterolemia in August 2023; and AZD0780 from AstraZeneca which is being evaluated in an ongoing Phase 2 clinical trial.

We are aware of other gene editing and epigenetic editing programs targeting the *PCSK9* gene in preclinical development. Precision Biosciences, Inc., or Precision, has published preclinical data showing long-term stable reduction of *PCSK9* and 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 FH in 2022. In January 2023, Precision announced that it had decided to cease pursuit of this program with iECURE as a partner, with plans to provide additional guidance on whether and when this medicine will advance into clinical testing in the future. Additionally, in 2022, CRISPR Therapeutics, or CRISPR, announced CTX330, its research stage *in vivo* gene editing program targeting *PCSK9.* In 2023, both Tune Therapeutics and Chroma Medicine, Inc. announced preclinical data for each of their preclinical stage epigenetic editing programs targeting *PCSK9*.

Evinacumab, which is a mAb targeting ANGPTL3 protein that is marketed by Regeneron, is approved by the FDA for the treatment of patients with HoFH and has additionally been evaluated in Phase 2 studies of patients with refractory hypercholesterolemia and either ASCVD or HeFH, and severe hypertriglyceridemia.

We are aware of several product candidates in clinical development that target *ANGPTL3* as a mechanism to lower LDL-C and reduce the risk of ASCVD, including zodasiran, a siRNA targeting *ANGPTL3* being evaluated by Arrowhead Pharmaceuticals, Inc., or Arrowhead, in Phase 2 clinical trials of patients with HoFH and patients with mixed dyslipidemia and for which Arrowhead announced data in November 2023. In addition, Lilly is evaluating a siRNA targeting ANGPTL3 protein in a Phase 2 clinical trial in adults with mixed dyslipidemia, and in 2023, CRISPR initiated a Phase 1 clinical trial for CTX310, its gene editing program targeting *ANGPTL3*.

Several investigational medicines designed to reduce lipoprotein(a), or Lp(a), are currently in development. These include pelacarsen, an antisense oligonucleotide licensed by Novartis from Ionis Pharmaceuticals in 2019, which is being evaluated in the Phase 3 Lp(a) HORIZON cardiovascular outcomes study in patients with elevated Lp(a) and CVD, with topline results expected in 2025. Olpasiran is an investigational siRNA medicine targeting *LPA* licensed by Amgen from Arrowhead, which was shown to lower Lp(a) concentrations in patients with established ASCVD and elevated Lp(a) concentrations. The potential for olpasiran to reduce cardiovascular events in patients with existing ASCVD and elevated Lp(a) is being evaluated in the Phase 3 OCEAN(a) trial, which was initiated in 2022 with plans for study completion in 2026. Lepodisiran is a GalNAc-conjugated siRNA being evaluated by Lilly in a Phase 3 clinical trial. In addition, zerlasiran is an investigational siRNA medicine that Silence Therapeutics plc, or Silence Therapeutics, is evaluating in an ongoing Phase 2 trial of patients with elevated Lp(a) concentrations and high risk for ASCVD events, for which Silence Therapeutics announced topline results in June 2024. In 2024, CRISPR initiated a Phase 1 clinical trial for CTX320, its gene editing program targeting *LPA*.

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 generic products. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium to competitive biosimilar generic 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 industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and 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 public health epidemics or pandemics, including the COVID-19 pandemic, terrorist attacks, wars or other armed conflicts, geopolitical tensions, such as the ongoing war between Israel and Hamas and ongoing war 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.

In addition, we currently rely on foreign third-party manufacturers, including those in China. Foreign third-party manufacturers may be subject to U.S. legislation, including sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material or services available to us, delay the procurement or supply of such material or services or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. Moreover, in January 2024, the U.S. House of Representatives introduced the BIOSECURE Act (H.R. 7085) and the Senate advanced a substantially similar bill (S.3558), which legislation, if passed and enacted into law, would have the potential to restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies “of concern,” without losing the ability to contract with, or otherwise receive funding from, the U.S. government. It is possible some of our contractual counterparties could be impacted by this legislation.

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 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. Reimbursement agencies in Europe may be more conservative than the Centers for Medicare & Medicaid Services, or CMS, in the United States. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries.

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 may need to obtain additional 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 Therapeutic Products 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.

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 pre-specified 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. The FDA has only recently approved the first e*x vivo* gene editing therapeutic product, CASGEVY™ for the treatment of sickle cell disease.

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.

In addition, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act, or the APA. Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Further, our ability to develop and market new products may be impacted by ongoing litigation challenging the FDA's approval of mifepristone. Specifically, in April 2023, the U.S. District Court for the Northern District of Texas stayed the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various conditions adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market, but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone that the FDA authorized in 2016 and 2021 were arbitrary and capricious. In June 2024, the U.S. Supreme Court reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. Depending on the outcome of this litigation, if it continues, our ability to develop new drug product candidates and to maintain approval of existing drug products and measures adopted under a REMS is at risk and our efforts to develop and market new drug products could be delayed, undermined or subject to protracted litigation.

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 our collaborators 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.

We could face heightened risks with respect to obtaining marketing authorization in the United Kingdom as a result of the United Kingdom's withdrawal from the European Union, or Brexit. As of January 2021, the MHRA is now the sole decision maker for marketing authorizations of pharmaceutical products in the United Kingdom, except for Northern Ireland, which is subject to EU rules under the Northern Ireland Protocol. The United Kingdom and the European Union have however agreed to the Windsor Framework which fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the United Kingdom. Once implemented, the changes introduced by the Windsor Framework will result in the MHRA being responsible for approving all medicinal products destined for the United Kingdom market (including Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. 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.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the European Union pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (including potentially reducing the duration of regulatory data protection and revising the eligibility for expedited pathways) was published in April 2023, and the European Parliament has requested several amendments. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term.

We do not have any experience commercializing products outside of the United States. 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, Innovative Licensing and Access Pathway designation in the United Kingdom, 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 equally pursue some of the post-Brexit UK MHRA procedures to prioritize access to new medicines that will benefit patients, such as a 150-day assessment, a rolling review procedure and an innovative licensing and access pathway, or ILAP. ILAP aims to accelerate the time to market and to facilitate patient access to medicines, including new chemical entities, biological medicines, new indications and repurposed medicines. We received our innovation passport, which is the point of entry into the ILAP, from the MHRA in February 2023. Product developers that benefit from ILAP will be provided with advice on clinical trial design to ensure optimal data generation for both regulatory approval and health technology appraisal.

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 currently 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 pre-existing 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 in December 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." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. In January 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA or Congress 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 or Congress may make to its orphan drug regulations and policies, our business could be adversely impacted.

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 and manufacturing, 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, including a requirement to implement a REMS.

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. 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. 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.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in October 2023, the FDA published draft guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This

draft guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. In addition, under the Pre-Approval Information Exchange Act signed into law as part of the Consolidated Appropriations Act of 2023, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

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. Further, the FDA and other agencies may experience disruptions due to public health epidemics or pandemics, such as the FDA's delays in domestic and foreign inspections during the COVID-19 pandemic. 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. 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.

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. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- 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. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- 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 physicians and their immediate family members and applicable group purchasing organizations, and, as of January 2022, requires 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 will remain in effect through the first half of 2032. 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 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.

Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010 (PAYGO) sequester for two years, through the end of 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriations Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into 2032 and lowers the payment reduction percentages in 2030 and 2031.

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, in December 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, in June 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. In January 2021, however, President Biden revoked those orders and issued an 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 directed the HHS to create a special enrollment period for the Health Insurance Marketplace in response to the COVID-19 pandemic, which period ended in June 2023.

In the European Union in December 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the HTA entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The HTA intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

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.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and such actions 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, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, in December 2021, CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Nine states have passed laws allowing for the importation of drugs from Canada. Certain of these states have submitted Section 804 Importation Program proposals and are awaiting FDA approval. In January 2024, the FDA authorized the importation of mass medications from Canada into Florida. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which has been delayed until January 1, 2032 by the Inflation Reduction Act, or IRA.

The IRA has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (which were first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or “catastrophic period” of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and adding price caps on annual out-of-pocket expenses, any of which could have potential pricing and reporting implications. Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition. In June 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce and pharmaceutical companies, have also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. There have been various decisions by the courts considering these cases since they were filed. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.

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, 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 and access. 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.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, 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, 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 addition to potential enforcement by HHS, we are also potentially subject to privacy enforcement from the Federal Trade Commission, or FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be “unfair” under Section 5 of the FTC Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The agency is also in the process of developing rules related to commercial surveillance and data security that may impact our business. We will need to account for the FTC’s evolving rules and guidance for proper privacy and data security practices in order to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and data security practices, which may impact our business. We may also be required to pay fines as part of a settlement (depending on the nature of the alleged violations). If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements.

States are also active in creating specific rules relating to the processing of personal information. In 2018, California passed into law the California Consumer Privacy Act, or 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 General Data Protection Regulation, or 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. In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act, or the CPRA, which went into effect on January 1, 2023, and significantly expanded 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. The CPRA also created a new enforcement agency—the California Privacy Protection Agency—whose sole responsibility is to enforce the CPRA, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, a number of other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime over the next several years. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data (which includes health data in some cases). Some of the provisions of these laws may apply to our business activities. 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 group of companies 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. This CJEU decision has resulted in increased scrutiny on data transfers generally and may 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.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the EU-U.S. Privacy Shield. The European Commission adopted the adequacy decision in July 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business internationally.

Following the withdrawal of the United Kingdom from the European Union, the United Kingdom's Data Protection Act 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. In relation to data transfers, both the United Kingdom and the European Union have determined, through separate "adequacy" decisions, that data transfers between the two jurisdictions are in compliance with the U.K.'s Data Protection Act 2018 and the GDPR, respectively. In October 2023, the United Kingdom and the United States implemented a "U.S.-U.K. data bridge," which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer data from the United Kingdom to the United States. Any changes or updates to these developments have the potential to impact our business.

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 the 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, Frederick Fiedorek, M.D., our chief medical officer, and Troy Lister, Ph.D., our chief scientific 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 war 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 and could include the use of artificial intelligence and machine learning to launch more automated, targeted and coordinated attacks on targets. 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.

While we have not experienced any material losses relating to cyber-attacks or security breaches, we have been the subject of hacking attempts that have resulted in limited breaches of our systems. 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 cyber-attacks or security 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 our ongoing or planned 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 19.2% of our common stock as of August 1, 2024. 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 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 be sustained. As a result, 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 clinical trials or preclinical studies 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;
- announcements by us or our competitors of significant acquisitions, in-licensing arrangements, strategic partnerships, joint ventures, or collaborations;
- 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;
- announcement or expectation of additional financing efforts;
- 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; and
- 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, cash equivalents and marketable securities and may not use them effectively.

Our management has broad discretion in the application of our cash, cash equivalents and marketable securities 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.

Sales of a substantial number of shares of our common stock 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 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 registration statements on Form S-8 to register all of the shares of common stock that we were able to issue under our equity compensation plans. 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 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 are incurring 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 of the Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal control over financial reporting and our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting. Compliance with Section 404 has been and will continue to be both costly and time-consuming for our management. If we have an unremediated material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm. 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% and limiting the deduction for NOLs arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income. In addition, beginning in 2022, the Tax Act eliminated the option to deduct research and development expenditures currently and generally requires corporations to capitalize and amortize them over five years or 15 years (for expenditures attributable to foreign research).

In addition to the CARES Act, as part of Congress' response to the COVID-19 pandemic, economic relief legislation was enacted in 2020 and 2021 containing tax provisions, and the IRA, which introduced a number of new tax provisions, was signed into law in August 2022. The IRA in particular imposes a 1% excise tax on certain stock repurchases by publicly traded corporations which generally applies to any acquisition by the publicly traded corporation (or certain of its affiliates) of stock of the publicly traded corporation in exchange for money or other property (other than stock of the corporation itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. Regulatory guidance under the Tax Act, the IRA 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. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the IRA 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 ongoing war between Israel and Hamas, the ongoing war 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, use of proceeds, and issuer purchases of equity securities

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 June 30, 2024, 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 marketable securities. 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 5. Other information

(c) Director and Officer Trading Arrangements

None of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the quarterly period covered by this report.

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	Second Amended and Restated Bylaws 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 February 17, 2023).
10.1*†	Separation Agreement, dated May 30, 2024, by and between the Registrant and Andrew Bellinger.
10.2*	Advisor Agreement, dated May 30, 2024, by and between the Registrant and Andrew Bellinger.
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: August 8, 2024

By: /s/ Sekar Kathiresan

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

Date: August 8, 2024

By: /s/ Allison Dorval

Allison Dorval
Chief Financial Officer
Principal Financial and Accounting Officer

Exhibit 10.1

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.

VIA ELECTRONIC MAIL

May 23, 2024 (as amended May 29, 2024)

Andrew Bellinger

Dear Andrew:

This letter agreement memorializes our discussions about your transition and separation from Verve Therapeutics, Inc. (the "**Company**"). As we discussed, provided you (a) sign and return to me, no later than the close of business on May 30, 2024, this letter agreement and the Advisor Agreement (as defined below), (b) do not rescind your acceptance of this letter agreement within seven (7) business days thereafter, (c) sign and return on, but not before, the Separation Date (as defined below) the Additional Release of Claims attached hereto as Attachment B (the "**Additional Release**"), (d) do not revoke your acceptance of the Additional Release within seven (7) calendar days thereafter (the "**Additional Release Revocation Period**"), and (e) comply with the obligations set forth in Sections 3, 4, 5 and 6 herein and in the Additional Release (the foregoing provisions (a) through (e) collectively, the "**Severance Conditions**"), you will remain an employee of the Company, pursuant to the terms and conditions hereof, through the Separation Date and the Company will provide you with the severance benefits set forth in paragraph 2 below. By signing, returning, and not rescinding your acceptance of this letter agreement and then signing, returning, and not revoking your acceptance of the Additional Release, you will be entering into binding agreements with the Company and will be agreeing to the terms and conditions set forth herein and therein. Therefore, you are advised to consult with an attorney before signing this letter agreement and the Additional Release.

The following numbered paragraphs set forth the terms and conditions that will apply if you satisfy the Severance Conditions:

1. **Separation Date; Transition Period; Resignation** – Your effective date of separation from the Company will be June 21, 2024 (the "**Separation Date**"). The period between the effective date of this letter agreement and the Separation Date will be a transition period (the "**Transition Period**"), during which you will continue to serve as the Company's Chief Scientific Officer. During the Transition Period, the Employment Agreement between you and the Company dated June 11, 2021, as amended by that First Amendment to Employment Agreement dated January 1, 2024 (together, the "**Employment Agreement**") will remain in full force and effect; provided, however, that you may only be terminated by the Company for Cause (as defined in the Employment Agreement) during the Transition Period. You hereby resign, effective as of the Separation Date, from any and all positions you hold as an officer of the Company, and agree that you will execute and deliver any documents reasonably necessary to effectuate such resignations.

2. **Description of Severance Benefits** – Subject to your satisfaction of the Severance Conditions, the Company will provide you with the following severance benefits (the "**severance benefits**"):

a. **Advisory Engagement**. The Company will engage you as an Advisor pursuant to the terms and conditions set forth in the Advisor Agreement attached hereto as Attachment A (the "**Advisor Agreement**"). You acknowledge and agree that notwithstanding your service as an Advisor and the terms of any applicable equity awards and/or agreements, you shall cease vesting in any

outstanding equity awards you hold as of the Separation Date and shall not continue to vest in any such award as a result of your service as an Advisor to the Company.

b. **Severance Pay.** The Company will pay to you $510,000.00, less all applicable taxes and withholdings, as severance pay (an amount equivalent to twelve (12) months of pay at your current base salary rate). This severance pay will be paid in substantially equal installments in accordance with the Company's regular payroll practices, but in no event shall payments begin earlier than the Company's first regular payroll cycle following expiration of the Additional Release Revocation Period (the "**Initial Payment Date**").

c. **Target Bonus.** The Company will pay to you, in one lump sum on the Initial Payment Date, $153,765.00, less all applicable taxes and withholdings (an amount equivalent to 67% of your 2024 Target Bonus (as defined in the Employment Agreement)).

d. **COBRA Benefits**. Should you timely elect and be eligible to continue receiving group health insurance pursuant to the "COBRA" law, the Company will, beginning on the Separation Date and continuing until the earliest to occur of (x) twelve (12) months following the Separation Date, (y) the date on which you have secured other employment, and (z) the date on which you are no longer eligible for coverage under COBRA (as applicable, the "**COBRA Contribution Period**"), continue to pay the share of the premiums for such coverage to the same extent it was paying such premiums on your behalf immediately prior to the Separation Date. The remaining balance of any premium costs during the COBRA Contribution Period, and all premium costs thereafter, shall be paid by you on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation. You agree that, should you secure other employment or cease to be eligible for coverage under COBRA prior to the date that is twelve (12) months following the Separation Date, you will so inform the Company in writing within five (5) business days.

e. **Equity Acceleration.** As of the expiration of the Additional Release Revocation Period, the vesting of each equity award granted to you prior to June 16, 2021 shall be accelerated such that such number of shares that would have vested had you remained employed by the Company through March 21, 2025 will become automatically vested and exercisable.

f. **Attorney's Fees Reimbursement**. You shall be reimbursed for attorneys' fees and any other professional services fees incurred in the negotiation of this Agreement, e.g., financial and/or tax advisory services, up to a maximum of $5,000 and subject to the submission of a summary invoice(s) from your professional service advisors, which for the avoidance of doubt shall not include any confidential or privileged information. You shall be reimbursed within thirty (30) calendar days of the submission of any such invoice(s). For the avoidance of doubt, any such reimbursements shall be subject to all applicable taxes and withholdings.

You acknowledge that the severance benefits exceed the Company's obligations under the Employment Agreement, and that you will not be eligible for, nor shall you have a right to receive, any payments or benefits from the Company following the Separation Date other than as set forth in this paragraph 2. You further acknowledge that your right to receive and retain the severance benefits is contingent upon your timely and full compliance with all of your obligations herein.

3. **Release of Claims** – In consideration of your continued employment with the Company through the Transition Period and the severance benefits, both of which you acknowledge you would not otherwise be entitled to receive, you hereby fully, forever, irrevocably and unconditionally release, remise and discharge the Company, its past and present affiliates, subsidiaries, parent companies, predecessors, and successors, and all of their respective past and present officers, directors, stockholders, partners,

members, employees, agents, representatives, plan administrators, attorneys, insurers and fiduciaries (each in their individual and corporate capacities) (collectively, the "**Released Parties**") from any and all claims, charges, complaints, demands, actions, causes of action, suits, rights, debts, sums of money, costs, accounts, reckonings, covenants, contracts, agreements, promises, doings, omissions, damages, executions, obligations, liabilities, and expenses (including attorneys' fees and costs), of every kind and nature that you ever had or now have against any or all of the Released Parties, whether known or unknown, including, but not limited to, any and all claims arising out of or relating to your employment with and/or separation from the Company, including, but not limited to, all claims under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., the Americans With Disabilities Act of 1990, 42 U.S.C. § 12101 et seq., the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 2000ff et seq., the Family and Medical Leave Act, 29 U.S.C. § 2601 et seq., the Worker Adjustment and Retraining Notification Act ("WARN"), 29 U.S.C. § 2101 et seq., the Rehabilitation Act of 1973, 29 U.S.C. § 701 et seq., Executive Order 11246, Executive Order 11141, the Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq., and the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq., all as amended; all claims arising out of the Massachusetts Fair Employment Practices Act, Mass. Gen. Laws ch. 151B, § 1 et seq., the Massachusetts Civil Rights Act, Mass. Gen. Laws ch. 12, §§ 11H and 11I, the Massachusetts Equal Rights Act, Mass. Gen. Laws. ch. 93, § 102, Mass. Gen. Laws ch. 214, § 1C (Massachusetts right to be free from sexual harassment law), the Massachusetts Labor and Industries Act, Mass. Gen. Laws ch. 149, § 1 et seq., Mass. Gen. Laws ch. 214, § 1B (Massachusetts right of privacy law), the Massachusetts Parental Leave Act, Mass. Gen. Laws ch. 149, § 105D, the Massachusetts Paid Family and Medical Leave Act, Mass. Gen. Laws ch. 175m, § 1, et seq., the Massachusetts Earned Sick Time Law, Mass. Gen. Laws ch. 149, § 148c, and the Massachusetts Small Necessities Leave Act, Mass. Gen. Laws ch. 149, § 52D, all as amended; all rights and claims under the Massachusetts Wage Act, Mass. Gen. Laws ch. 149, § 148 et seq., as amended (Massachusetts law regarding payment of wages and overtime), including any rights or claims thereunder to unpaid wages, including overtime, bonuses, commissions, and accrued, unused vacation time; all common law claims including, but not limited to, actions in defamation, intentional infliction of emotional distress, misrepresentation, fraud, wrongful discharge, and breach of contract (including, without limitation, all claims arising out of or related to the Employment Agreement); all claims to any non-vested ownership interest in the Company or any of its affiliates, contractual or otherwise; all state and federal whistleblower claims to the maximum extent permitted by law; and any claim or damage arising out of your employment with and/or separation from the Company (including a claim for retaliation) under any common law theory or any federal, state or local statute or ordinance not expressly referenced above. *Notwithstanding the foregoing, nothing in this release of claims or in this letter agreement shall be deemed to prohibit you from filing a charge with, or participating in any investigation or proceeding before, any local, state or federal government agency, including, without limitation, the Equal Employment Opportunity Commission or a state or local fair employment practices agency. You retain the right to participate in any such action but not the right to recover money damages or other individual legal or equitable relief awarded by any such governmental agency, including any payment, benefit, or attorneys' fees, and hereby waive any right or claim to any such relief; provided, however, that nothing herein shall bar or impede in any way your ability to seek or receive any monetary award or bounty from any governmental agency or regulatory or law enforcement authority in connection with protected whistleblower activity. Further, you acknowledge and agree that you are not releasing the Company from any obligation set forth in this letter agreement or from any obligation which as a matter of law cannot be released, including, without limitation, obligations under the workers compensation or unemployment laws.*

4. **Continuing Obligations; Non-Compete** – You acknowledge and reaffirm your continuing obligations to the Company as set forth in the At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement dated March 9, 2020 between you and the Company (the "**Confidentiality Agreement**"), which obligations remain in full force and effect. In addition, and as an express condition of your eligibility to serve as an Advisor pursuant to the terms and conditions of the

Advisor Agreement, you agree that, commencing on the Separation Date and continuing until the one (1)-year anniversary of the termination of the Advisor Agreement, you will not, anywhere in North America or Europe or in any geographical areas that the Company does business or has done business as of the Separation Date, directly or indirectly, whether as an owner, partner, officer, director, employee, consultant, investor, lender or otherwise (except as the passive holder of not more than 1% of the outstanding stock of a publicly-held company), engage or assist others in engaging in any business or provide services to any business that has any program(s) targeting [**] (each, a "**Competitive Business**"); provided, however, that with the Company's prior written consent, you may work for a division, entity or subgroup of a person or entity that engages in the Competitive Business so long as such division, entity or subgroup does not engage in the Competitive Business. Upon acknowledged delivery of your request for any such written consent, the Company shall use its best efforts to respond within fourteen (14) calendar days. If any restriction set forth in this paragraph 4 is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographical area, it shall be interpreted to extend only over the maximum period of time, range or activities or geographical area as to which it may be enforceable.

5. **Disclosures –**

a. **Non-Disparagement** – Except for Permitted Disclosures (as set forth in paragraph 5(c) below), you agree not to, in public or private, make any false, disparaging, derogatory or defamatory statements, online (including, without limitation, on any social media, networking, or employer review site) or otherwise, to any person or entity, including, but not limited to, any media outlet, industry group, financial institution or current or former board member, employee, consultant, client, or customer of the Company, regarding the Company or any of the other Released Parties, or regarding the business affairs, business prospects, or financial condition of the Company or any of the other Released Parties. In return, the Company agrees to instruct the members of its management team not to, either during the Transition Period or thereafter, in public or private, make any false, disparaging, derogatory or defamatory statements, online (including, without limitation, on any social media, networking, or employer review site) or otherwise, to any third party regarding you.

b. **Confidentiality** – Except for Permitted Disclosures (as set forth in paragraph 5(c) below), you agree to maintain as confidential and not to disclose the contents of the negotiations and discussions resulting in this letter agreement.

c. **Permitted Disclosures** – Nothing in this letter agreement, including paragraphs 5(a) and 5(b) above, the Confidentiality Agreement, or elsewhere prohibits or restricts you from communicating with, or voluntarily providing information you believe indicates possible or actual violations of the law to, local, state or federal government agencies, any legislative body, law enforcement, or any self-regulatory organization (including but not limited to the Securities & Exchange Commission). You are not required to notify the Company of any such communications. Further, notwithstanding your confidentiality and nondisclosure obligations, you are hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in

the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

6. **Cooperation** – You agree to make yourself reasonably available and to cooperate with the Company in: (i) any internal investigation; (ii) any investigation, defense or prosecution of any claims or actions which already have been brought, are currently pending, or which may be brought in the future against the Company by a third party or by or on behalf of the Company against any third party, whether before a state or federal court, any state or federal government agency, or a mediator or arbitrator; and/or (iii) any other administrative, regulatory, or judicial inquiry, investigation, proceeding or arbitration. The Company will reimburse you for any reasonable costs and expenses approved in advance by the Company and incurred in connection with providing such cooperation under this paragraph 6. You understand and agree that your reasonable cooperation includes, but is not limited to, making yourself available to the Company upon reasonable notice for interviews and factual investigations; appearing at the Company's request to give testimony without requiring service of a subpoena or other legal process; volunteering to the Company pertinent information; and turning over all relevant documents which are in or may come into your possession. The term "cooperation" does not mean that you must provide information that is favorable to the Company; it means only that you will provide truthful information within your knowledge and possession upon request of the Company. You further agree that, to the extent permitted by law, you will notify the Company promptly in the event that you are served with a subpoena (other than a subpoena issued by a government agency), or in the event that you are asked to provide a third party (other than a government agency) with information concerning any actual or potential complaint or claim against the Company.

7. **Amendment and Waiver** – This letter agreement and the Additional Release shall be binding upon the parties and may not be waived or modified in any manner, except by an instrument in writing of concurrent or subsequent date signed by duly authorized representatives of the parties hereto. This letter agreement and the Additional Release are binding upon and shall inure to the benefit of the parties and their respective agents, assigns, heirs, executors, successors and administrators. No delay or omission by either party in exercising any right under this letter agreement or the Additional Release shall operate as a waiver of that or any other right. A waiver or consent given by either party on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

8. **Validity** – Should any provision of this letter agreement or the Additional Release be declared or be determined by any court of competent jurisdiction to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term or provision shall be deemed not to be a part of this letter agreement or the Additional Release.

9. **Nature of Agreement –** You understand and agree that this letter agreement, together with the Additional Release, is a severance agreement and does not constitute an admission of liability or wrongdoing on the part of the Company or any of the other Released Parties.

10. **Acknowledgments –** You acknowledge that you have been given a reasonable amount of time to consider this letter agreement and at least twenty-one (21) days to consider the Additional Release, and that the Company is hereby advising you to consult with an attorney of your own choosing prior to signing this letter agreement and the Additional Release. You understand that you may rescind your acceptance of this letter agreement for a period of seven (7) business days after you sign this letter agreement by notifying me in writing, and that this letter agreement shall not be effective or enforceable until the expiration of this seven (7) business day rescission period. You further understand that you may revoke your acceptance of the Additional Release during the Additional Release Revocation Period by notifying me in writing, and the Additional Release shall not be effective or enforceable until the

expiration of the Additional Release Revocation Period. You understand and agree that by entering into the Additional Release, you will be waiving any and all rights or claims you might have under the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, and that you have received consideration beyond that to which you were previously entitled.

11. **Voluntary Assent** – You affirm that no other promises or agreements of any kind have been made to or with you by any person or entity whatsoever to cause you to sign this letter agreement or the Additional Release, and that you fully understand the meaning and intent of this letter agreement and the Additional Release. You further state and represent that you have carefully read this letter agreement and the Additional Release, understand the contents herein, freely and voluntarily assent to all of the terms and conditions hereof, and sign your name of your own free act.

12. **Applicable Law; Forum** – This letter agreement and the Additional Release shall be interpreted and construed by the laws of the Commonwealth of Massachusetts, without regard to conflict of laws provisions. Any action, suit or other legal proceeding arising out of, under or in connection with this letter agreement or the Additional Release shall be subject to arbitration in accordance with Section 11 of the Confidentiality Agreement.

13. **Entire Agreement** – This letter agreement and the Additional Release constitute the entire understanding and agreement between the parties hereto with respect to your continued employment with the Company through the Transition Period, severance benefits, and the settlement of claims against the Company and the other Released Parties and cancel all previous oral and written negotiations, agreements, commitments and writings in connection therewith.

14. **Tax Acknowledgement** – In connection with the severance benefits provided to you pursuant to this letter agreement and the Additional Release, the Company shall withhold and remit to the tax authorities the amounts required under applicable law, and you shall be responsible for all applicable taxes with respect to such benefits under applicable law. You acknowledge that you are not relying upon advice or representation of the Company with respect to the tax treatment of any of the severance benefits.

Very truly yours,

By: /s/ Andrew D. Ashe
Andrew D. Ashe
Chief Operating Officer & General Counsel

I hereby agree to the terms and conditions set forth above. I have been given a reasonable amount of time to consider this letter agreement and I have chosen to execute this on the date below. I intend that this letter agreement will become a binding agreement between me and the Company if I do not rescind my acceptance in seven (7) business days. I understand that the severance benefits described in paragraph 2 of this letter agreement are conditioned upon my timely execution, return, and non-revocation of the Additional Release.

/s/ Andrew Bellinger — 5/30/2024
Andrew Bellinger — Date

To be returned in a timely manner as set forth on the first page of this letter agreement.

ATTACHMENT A

ADVISOR AGREEMENT

This Advisor Agreement (the "**Agreement**"), made this ___ day of May, 2024, is entered into by and between Verve Therapeutics, Inc. (the "**Company**"), and Andrew Bellinger (the "**Advisor**"), and will be effective as of the day immediately following the Separation Date (hereinafter, the "**Effective Date**"). Capitalized terms used but not defined herein have the meanings set forth in the letter agreement to which this Agreement is attached as Attachment A (the "**Separation Agreement**").

WHEREAS, the Company and the Advisor desire to establish the terms and conditions under which the Advisor will provide services to the Company.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties hereto, the parties agree as follows:

1 Services. The Advisor agrees to perform for the Company such advisory services as the Company may reasonably request from time to time (collectively, the "**Services**"). It is expected that the Advisor will in no event perform (or be asked to perform) more than 20 hours of Services per month.

2 Term. The term of this Agreement shall commence on the Effective Date and continue until the Agreement is terminated in accordance with the provisions of Section 4 below (such period, the "**Advisory Period**").

3 Compensation.

3.1 Advisory Fees. The Company shall pay the Advisor a fee of $200 per hour for Services performed during the Advisory Period. At the end of any month in which the Advisor performs Services, the Advisor shall submit to the Company an itemized statement of the Services performed, including the number of hours worked and the project to which the Services relate. Within thirty (30) days after receipt of the statement, the Company shall pay to the Advisor the advisory fees for all undisputed Services invoiced in the statement. The Company shall also reimburse the Advisor for all reasonable and necessary out-of-pocket business expenses incurred by the Advisor in performing the Services, subject to prior approval by the Company and pursuant to the Company's normal policies and procedures for expense verification and documentation. The Advisor shall not be entitled to any benefits, coverages or privileges, including, without limitation, health insurance, social security, unemployment, medical or pension payments, made available to employees of the Company.

3.2 Extension of Exercisability Period for Vested Stock Options. As additional consideration for the Advisor's performance of the Services, and notwithstanding the terms of any equity awards and/or agreements the Advisor has received from the Company (the "**Awards**"), the Awards shall remain outstanding and exercisable during the Advisory Period and for such period of time following the Advisory Period as is set forth in the terms of the Awards. For the avoidance of doubt, and without superseding any provision of an Award, the Advisor's vested equity will remain exercisable for a period of three months following any termination of this Agreement pursuant to Section 4 below other than a termination pursuant to Section 4.2(a) resulting from a violation of the Separation Agreement and/or Confidentiality Agreement. The Advisor acknowledges and agrees that notwithstanding the terms of any Award, the Advisor shall cease vesting in any outstanding Award the Advisor holds as of the Separation Date and shall not continue to vest in any such Award as a result of this Agreement and/or the Advisor's provision of Services hereunder.

4 Termination.

4.1 Termination for Convenience. This Agreement may be terminated by either the Company or the Advisor for any reason or no reason upon not less than thirty (30) days prior written notice to the other party; provided, however, that the Company may not terminate this Agreement pursuant to this Section 4.1 prior to the two-year anniversary of the Effective Date.

4.2 Termination for Breach. This Agreement may also be terminated by the Company (a) upon twenty-four (24) hours prior written notice to the Advisor, if the Advisor has materially breached this Agreement, the Separation Agreement, and/or the Confidentiality Agreement; or (b) immediately if the Advisor fails to timely execute the Separation Agreement or revokes his acceptance of the Separation Agreement.

5 Cooperation. The Advisor shall use the Advisor's best efforts in the performance of the Advisor's obligations under this Agreement. The Company shall provide such access to its information and property as may be reasonably required in order to permit the Advisor to perform the Advisor's obligations hereunder. The Advisor shall reasonably cooperate with the Company's personnel, shall not interfere with the conduct of the Company's business, and shall observe all rules, regulations and security requirements of the Company concerning the safety of persons and property.

6 Proprietary Information and Inventions.

6.1 Proprietary Information.

(a) The Advisor acknowledges that the Advisor's relationship with the Company is one of high trust and confidence and that in the course of the Advisor's service to the Company, the Advisor will have access to and contact with Proprietary Information (as defined below). The Advisor will not disclose any Proprietary Information to any person or entity other than employees of the Company or use the same for any purposes (other than in the performance of the Services) without written approval by an officer of the Company, either during or after the Advisory Period, unless and until such Proprietary Information has become public knowledge without fault by the Advisor.

(b) For purposes of this Agreement, "**Proprietary Information**" shall mean, by way of illustration and not limitation, all information, whether or not in writing, whether or not patentable and whether or not copyrightable, of a private, secret or confidential nature, owned, possessed or used by the Company, concerning the Company's business, business relationships or financial affairs, including, without limitation, any Invention (as defined below), formula, vendor information, customer information, apparatus, equipment, trade secret, process, research, report, technical or research data, clinical data, know-how, computer program, software, software documentation, hardware design, technology, product, processes, methods, techniques, formulas, compounds, projects, developments, marketing or business plan, forecast, unpublished financial statement, budget, license, price, cost, customer, supplier or personnel information or employee list that is communicated to, learned of, developed or otherwise acquired by the Advisor in the course of Advisor's service as an Advisor to the Company.

(c) The Advisor agrees that all files, documents, letters, memoranda, reports, records, data sketches, drawings, models, laboratory notebooks, program listings, computer equipment or devices, computer programs or other written, photographic, or other tangible material containing Proprietary Information, whether created by the Advisor or others, which shall come into the Advisor's custody or possession, shall be and are the exclusive property of the Company to be used by the Advisor only in the performance of the Services and shall not be copied or removed from the Company's premises

except in the pursuit of the business of the Company. All such materials or copies thereof and all tangible property of the Company in the custody or possession of the Advisor shall be delivered to the Company, upon the earlier of (i) a request by the Company or (ii) the termination of this Agreement. After such delivery, the Advisor shall not retain any such materials or copies thereof or any such tangible property.

(d) The Advisor agrees that the Advisor's obligation not to disclose or to use information and materials of the types set forth in paragraphs (b) and (c) above, and the Advisor's obligation to return materials and tangible property set forth in paragraph (c) above extends to such types of information, materials and tangible property of customers of the Company or suppliers to the Company or other third parties who may have disclosed or entrusted the same to the Company or to the Advisor.

(e) The Advisor acknowledges that the Company from time to time may have agreements with other persons or with the United States Government, or agencies thereof, that impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. The Advisor agrees to be bound by all such obligations and restrictions that are known to the Advisor and to take all action necessary to discharge the obligations of the Company under such agreements.

(f) The Advisor's obligations under this Section 6.1 shall not apply to any information that (i) is or becomes known to the general public under circumstances involving no breach by the Advisor or others of the terms of this Section 6.1, (ii) is generally disclosed to third parties by the Company without restriction on such third parties, or (iii) is approved for release by written authorization of an officer of the Company. Further, nothing herein prohibits or restricts the Advisor from communicating with, or voluntarily providing information the Advisor believes indicates possible or actual violations of the law to, local, state or federal government agencies, any legislative body, law enforcement, or any self-regulatory organization (including but not limited to the Securities & Exchange Commission). The Advisor is not required to notify the Company of any such communications. In addition, notwithstanding the Advisor's confidentiality and nondisclosure obligations, the Advisor is hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

6.2 Inventions.

(a) All inventions, ideas, creations, discoveries, computer programs, works of authorship, data, developments, technology, designs, innovations and improvements (whether or not patentable and whether or not copyrightable) which are made, conceived, reduced to practice, created, written, designed or developed by the Advisor, solely or jointly with others or under Advisor's direction and whether during normal business hours or otherwise, (i) during the Advisory Period if related to the business of the Company or (ii) after the Advisory Period if derived from Proprietary Information (collectively under clauses (i) and (ii), "**Inventions**"), shall be the sole property of the Company. The Advisor hereby assigns to the Company all Inventions and any and all related patents, copyrights, trademarks, trade names, and other industrial and intellectual property rights and applications therefor, in the United States and elsewhere and appoints any officer of the Company as Advisor's duly authorized

attorney to execute, file, prosecute and protect the same before any government agency, court or authority. However, this paragraph shall not apply to Inventions which do not relate to the business or research and development conducted or planned to be conducted by the Company at the time such Invention is created, made, conceived or reduced to practice and which are made and conceived by the Advisor not during normal working hours, not on the Company's premises and not using the Company's tools, devices, equipment or Proprietary Information. The Advisor further acknowledges that each original work of authorship which is made by the Advisor (solely or jointly with others) within the scope of the Agreement and which is protectable by copyright is a "work made for hire," as that term is defined in the United States Copyright Act.

(b) The Advisor agrees that if, in the course of performing the Services, the Advisor incorporates into any Invention developed under this Agreement any preexisting invention, improvement, development, concept, discovery or other proprietary information owned by the Advisor or in which the Advisor has an interest ("**Prior Inventions**"), (i) the Advisor will inform the Company, in writing before incorporating such Prior Inventions into any Invention, and (ii) the Company is hereby granted a nonexclusive, royalty-free, perpetual, irrevocable, transferable worldwide license with the right to grant and authorize sublicenses, to make, have made, modify, use, import, offer for sale, sell, reproduce, distribute, modify, adapt, prepare derivative works of, display, perform, and otherwise exploit such Prior Inventions, without restriction, including, without limitation, as part of or in connection with such Invention, and to practice any method related thereto. The Advisor will not incorporate any invention, improvement, development, concept, discovery or other proprietary information owned by any third party into any Invention without the Company's prior written permission.

(c) Upon the request of the Company and at the Company's expense, the Advisor shall execute such further assignments, documents and other instruments as may be necessary or desirable to fully and completely assign all Inventions to the Company and to assist the Company in applying for, obtaining and enforcing patents or copyrights or other rights in the United States and in any foreign country with respect to any Invention. The Advisor also hereby waives all claims to moral rights in any Inventions.

(d) The Advisor shall promptly disclose to the Company all Inventions and will maintain adequate and current written records (in the form of notes, sketches, drawings and as may be specified by the Company) to document the conception and/or first actual reduction to practice of any Invention. Such written records shall be available to and remain the sole property of the Company at all times.

7 Exclusivity. The Company retains the right to contract with other companies and/or individuals for consulting services without restriction. Similarly, the Advisor retains the right to contract with other companies or entities for the Advisor's consulting services, subject to the Advisor's continued obligations to the Company, including as set forth in the Confidentiality Agreement and Separation Agreement.

8 Other Agreements; Warranty.

8.1 The Advisor hereby represents that, except as the Advisor has disclosed in writing to the Company, the Advisor is not bound by the terms of any agreement with any third party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of the Advisor's consultancy with the Company, to refrain from competing, directly or indirectly, with the business of such third party or to refrain from soliciting employees, customers or suppliers of such third party. The Advisor further represents that the Advisor's performance of all the terms of this Agreement and the performance of the Services do not and will not breach any agreement with any third party to

which the Advisor is a party (including, without limitation, any nondisclosure or non-competition agreement), and that the Advisor will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any current or previous employer or others.

8.2 The Advisor hereby represents, warrants and covenants that the Advisor has the skills and experience necessary to perform the Services, that Advisor will perform said Services in a professional, competent and timely manner, that the Advisor has the power to enter into this Agreement and that the Advisor's performance hereunder will not infringe upon or violate the rights of any third party or violate any federal, state or municipal laws.

9 Independent Contractor Status.

9.1 The Advisor shall perform all services under this Agreement as an "independent contractor" and not as an employee or agent of the Company. The Advisor is not authorized to assume or create any obligation or responsibility, express or implied, on behalf of, or in the name of, the Company or to bind the Company in any manner.

9.2 The Advisor shall have the right to control and determine the time, place, methods, manner and means of performing the Services. In performing the Services, the amount of time devoted by the Advisor on any given day will be entirely within the Advisor's control, and the Company will rely on the Advisor to put in the amount of time necessary to fulfill the requirements of this Agreement.

9.3 In the performance of the Services, the Advisor has the authority to control and direct the performance of the details of the Services, the Company being interested only in the results obtained. However, the Services contemplated by this Agreement must meet the Company's standards and approval and shall be subject to the Company's general right of inspection to secure their satisfactory completion.

9.4 The Advisor shall not use the Company's trade names, trademarks, service names or service marks without the prior approval of the Company.

9.5 The Advisor shall be solely responsible for all state and federal income taxes, unemployment insurance and social security taxes and for maintaining adequate workers' compensation insurance coverage.

10 Remedies. The Advisor acknowledges that any breach of the provisions of Sections 6 or 7 of this Agreement shall result in serious and irreparable injury to the Company for which the Company cannot be adequately compensated by monetary damages alone. The Advisor agrees, therefore, that, in addition to any other remedy the Company may have, the Company shall be entitled to enforce the specific performance of this Agreement by the Advisor and to seek both temporary and permanent injunctive relief (to the extent permitted by law) without the necessity of proving actual damages or posting a bond.

11 Notices. All notices required or permitted under this Agreement shall be in writing and will be either personally delivered, sent by reputable overnight courier service, mailed by first class mail, or sent via e-mail with a subject header that includes the word "Notice".

12 Pronouns. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns and pronouns shall include the plural, and vice versa.

13 Entire Agreement. This Agreement constitutes the entire agreement between the parties relating to the subject matter of this Agreement, and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement.

14 Amendment and Waiver. This Agreement may be amended, waived, or modified only by a written instrument executed by both the Company and the Advisor.

15 Non-Assignability of Contract. This Agreement is personal to the Advisor and the Advisor shall not have the right to assign any of the Advisor's rights or delegate any of the Advisor's duties without the express written consent of the Company. Any non-consented-to assignment or delegation, whether express or implied or by operation of law, shall be void.

16 Governing Law; Forum. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without giving effect to any choice or conflict of law provision or rule that would cause the application of laws of any other jurisdiction. Any action, suit or other legal proceeding arising out of, under or in connection with this Agreement shall be subject to arbitration in accordance with Section 11 of the Confidentiality Agreement.

17 Successors and Assigns. This Agreement shall be binding upon, and inure to the benefit of, both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to its assets or business; provided, however, that the obligations of the Advisor are personal and shall not be assigned by the Advisor.

18 Interpretation. If any restriction set forth in Section 6 is found by an arbitrator or any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range of activities or geographic area as to which it may be enforceable.

19 Survival. Sections 4 through 20 shall survive the termination of this Agreement.

20 Miscellaneous.

20.1 No delay or omission by either of the parties in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by either of the parties on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

20.2 The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

20.3 In the event that any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

[*Remainder of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, the parties hereto have executed this Advisor Agreement as of the date and year first above written.

COMPANY:

VERVE THERAPEUTICS, INC.

By: _____
Andrew D. Ashe
Chief Operating Officer & General Counsel

ADVISOR:

_____
Andrew Bellinger

ATTACHMENT B

ADDITIONAL RELEASE OF CLAIMS

1. **Release** – In consideration of the severance benefits set forth in the letter agreement to which this Additional Release of Claims (the "**Additional Release**") is attached, which you acknowledge you would not otherwise be entitled to receive, you hereby fully, forever, irrevocably and unconditionally release, remise and discharge the Company, its past and present affiliates, subsidiaries, parent companies, predecessors, and successors, and all of their respective past and present officers, directors, stockholders, partners, members, employees, agents, representatives, plan administrators, attorneys, insurers and fiduciaries (each in their individual and corporate capacities) (collectively, the "**Released Parties**") from any and all claims, charges, complaints, demands, actions, causes of action, suits, rights, debts, sums of money, costs, accounts, reckonings, covenants, contracts, agreements, promises, doings, omissions, damages, executions, obligations, liabilities, and expenses (including attorneys' fees and costs), of every kind and nature that you ever had or now have against any or all of the Released Parties, whether known or unknown, including, but not limited to, any and all claims arising out of or relating to your employment with and/or separation from the Company, including, but not limited to, all claims under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., the Americans With Disabilities Act of 1990, 42 U.S.C. § 12101 et seq., the Age Discrimination in Employment Act, 29 U.S.C. § 621 et seq., the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 2000ff et seq., the Family and Medical Leave Act, 29 U.S.C. § 2601 et seq., the Worker Adjustment and Retraining Notification Act ("WARN"), 29 U.S.C. § 2101 et seq., the Rehabilitation Act of 1973, 29 U.S.C. § 701 et seq., Executive Order 11246, Executive Order 11141, the Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq., and the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq., all as amended; all claims arising out of the Massachusetts Fair Employment Practices Act, Mass. Gen. Laws ch. 151B, § 1 et seq., the Massachusetts Civil Rights Act, Mass. Gen. Laws ch. 12, §§ 11H and 11I, the Massachusetts Equal Rights Act, Mass. Gen. Laws. ch. 93, § 102, Mass. Gen. Laws ch. 214, § 1C (Massachusetts right to be free from sexual harassment law), the Massachusetts Labor and Industries Act, Mass. Gen. Laws ch. 149, § 1 et seq., Mass. Gen. Laws ch. 214, § 1B (Massachusetts right of privacy law), the Massachusetts Parental Leave Act, Mass. Gen. Laws ch. 149, § 105D, the Massachusetts Paid Family and Medical Leave Act, Mass. Gen. Laws ch. 175m, § 1, et seq., the Massachusetts Earned Sick Time Law, Mass. Gen. Laws ch. 149, § 148c, and the Massachusetts Small Necessities Leave Act, Mass. Gen. Laws ch. 149, § 52D, all as amended; all rights and claims under the Massachusetts Wage Act, Mass. Gen. Laws ch. 149, § 148 et seq., as amended (Massachusetts law regarding payment of wages and overtime), including any rights or claims thereunder to unpaid wages, including overtime, bonuses, commissions, and accrued, unused vacation time; all common law claims including, but not limited to, actions in defamation, intentional infliction of emotional distress, misrepresentation, fraud, wrongful discharge, and breach of contract (including, without limitation, all claims arising out of or related to the Employment Agreement); all claims to any non-vested ownership interest in the Company or any of its affiliates, contractual or otherwise; all state and federal whistleblower claims to the maximum extent permitted by law; and any claim or damage arising out of your employment with and/or separation from the Company (including a claim for retaliation) under any common law theory or any federal, state or local statute or ordinance not expressly referenced above. *Notwithstanding the foregoing, nothing in this release of claims or in this Additional Release shall be deemed to prohibit you from filing a charge with, or participating in any investigation or proceeding before, any local, state or federal government agency, including, without limitation, the Equal Employment Opportunity Commission or a state or local fair employment practices*

agency. You retain the right to participate in any such action but not the right to recover money damages or other individual legal or equitable relief awarded by any such governmental agency, including any payment, benefit, or attorneys' fees, and hereby waive any right or claim to any such relief; provided, however, that nothing herein shall bar or impede in any way your ability to seek or receive any monetary award or bounty from any governmental agency or regulatory or law enforcement authority in connection with protected whistleblower activity. Further, you acknowledge and agree that you are not releasing the Company from any obligation set forth in the letter agreement or from any obligation which as a matter of law cannot be released, including, without limitation, obligations under the workers compensation or unemployment laws.

2. **Business Expenses and Final Compensation** – You acknowledge that you have been reimbursed by the Company for all business expenses incurred in conjunction with the performance of your employment and that no other reimbursements are owed to you. You further acknowledge that you have received payment in full for all services rendered in conjunction with your employment by the Company, including payment for all wages, bonuses, and accrued but unused vacation time, and that no other compensation is owed to you except as provided in the letter agreement.

3. **Return of Company Property** – You confirm that you have returned to the Company all keys, files, records (and copies thereof), equipment (including, but not limited to, computer hardware, software, printers, flash drives and other storage devices, wireless handheld devices, cellular phones, tablets, etc.), Company identification, and any other Company owned property in your possession or control, and that you have left intact all, and have otherwise not destroyed, deleted, or made inaccessible to the Company any, electronic Company documents, including, but not limited to, those that you developed or helped to develop during your employment, and that you have not (a) retained any copies in any form or media; (b) maintained access to any copies in any form, media, or location; (c) stored any copies in any physical or electronic locations that are not readily accessible or known to the Company or that remain accessible to you; or (d) sent, given, or made accessible any copies to any persons or entities that the Company has not authorized to receive such electronic or hard copies. You further confirm that you have cancelled all accounts for your benefit, if any, in the Company's name, including but not limited to, credit cards, telephone charge cards, cellular phone accounts, and computer accounts.

4. **Acknowledgments** – You acknowledge that you have been given at least twenty-one (21) days to consider this Additional Release, and that the Company is hereby advising you to consult with an attorney of your own choosing prior to signing this Additional Release. You understand that you may revoke your acceptance of this Additional Release for a period of seven (7) days after you sign this Additional Release by notifying me in writing, and the Additional Release shall not be effective or enforceable until the expiration of this seven (7) day revocation period. You understand and agree that by entering into this Additional Release, you are waiving any and all rights or claims you might have under the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, and that you have received consideration beyond that to which you were previously entitled.

5. **Voluntary Assent –** You affirm that no other promises or agreements of any kind have been made to or with you by any person or entity whatsoever to cause you to sign this Additional Release, and that you fully understand the meaning and intent of this Additional Release. You state and represent that you have had an opportunity to fully discuss and review the terms of this Additional Release with an attorney. You further state and represent that you have carefully read

this Additional Release, understand the contents herein, freely and voluntarily assent to all of the terms and conditions hereof, and sign your name of your own free act.

I hereby provide this Additional Release as of the current date and acknowledge that the execution of this Additional Release is in further consideration of the severance benefits, to which I acknowledge I would not be entitled if I did not enter into this Additional Release.

_____	_____
Andrew Bellinger	Date

Exhibit 10.2

ADVISOR AGREEMENT

This Advisor Agreement (the "**Agreement**"), made this 30th day of May, 2024, is entered into by and between Verve Therapeutics, Inc. (the "**Company**"), and Andrew Bellinger (the "**Advisor**"), and will be effective as of the day immediately following the Separation Date (hereinafter, the "**Effective Date**"). Capitalized terms used but not defined herein have the meanings set forth in the letter agreement to which this Agreement is attached as Attachment A (the "**Separation Agreement**").

WHEREAS, the Company and the Advisor desire to establish the terms and conditions under which the Advisor will provide services to the Company.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties hereto, the parties agree as follows:

1 Services. The Advisor agrees to perform for the Company such advisory services as the Company may reasonably request from time to time (collectively, the "**Services**"). It is expected that the Advisor will in no event perform (or be asked to perform) more than 20 hours of Services per month.

2 Term. The term of this Agreement shall commence on the Effective Date and continue until the Agreement is terminated in accordance with the provisions of Section 4 below (such period, the "**Advisory Period**").

3 Compensation.

3.1 Advisory Fees. The Company shall pay the Advisor a fee of $200 per hour for Services performed during the Advisory Period. At the end of any month in which the Advisor performs Services, the Advisor shall submit to the Company an itemized statement of the Services performed, including the number of hours worked and the project to which the Services relate. Within thirty (30) days after receipt of the statement, the Company shall pay to the Advisor the advisory fees for all undisputed Services invoiced in the statement. The Company shall also reimburse the Advisor for all reasonable and necessary out-of-pocket business expenses incurred by the Advisor in performing the Services, subject to prior approval by the Company and pursuant to the Company's normal policies and procedures for expense verification and documentation. The Advisor shall not be entitled to any benefits, coverages or privileges, including, without limitation, health insurance, social security, unemployment, medical or pension payments, made available to employees of the Company.

3.2 Extension of Exercisability Period for Vested Stock Options. As additional consideration for the Advisor's performance of the Services, and notwithstanding the terms of any equity awards and/or agreements the Advisor has received from the Company (the "**Awards**"), the Awards shall remain outstanding and exercisable during the Advisory Period and for such period of time following the Advisory Period as is set forth in the terms of the Awards. For the avoidance of doubt, and without superseding any provision of an Award, the Advisor's vested equity will remain exercisable for a period of three months following any termination of this Agreement pursuant to Section 4 below other than a termination pursuant to Section 4.2(a) resulting from a violation of the Separation Agreement and/or Confidentiality Agreement. The Advisor acknowledges and agrees that notwithstanding the terms of any Award, the Advisor shall cease vesting in any outstanding Award the Advisor holds as of the Separation Date and shall not continue to vest in any such Award as a result of this Agreement and/or the Advisor's provision of Services hereunder.

4 Termination.

4.1 Termination for Convenience. This Agreement may be terminated by either the Company or the Advisor for any reason or no reason upon not less than thirty (30) days prior written notice to the other party; provided, however, that the Company may not terminate this Agreement pursuant to this Section 4.1 prior to the two-year anniversary of the Effective Date.

4.2 Termination for Breach. This Agreement may also be terminated by the Company (a) upon twenty-four (24) hours prior written notice to the Advisor, if the Advisor has materially breached this Agreement, the Separation Agreement, and/or the Confidentiality Agreement; or (b) immediately if the Advisor fails to timely execute the Separation Agreement or revokes his acceptance of the Separation Agreement.

5 Cooperation. The Advisor shall use the Advisor's best efforts in the performance of the Advisor's obligations under this Agreement. The Company shall provide such access to its information and property as may be reasonably required in order to permit the Advisor to perform the Advisor's obligations hereunder. The Advisor shall reasonably cooperate with the Company's personnel, shall not interfere with the conduct of the Company's business, and shall observe all rules, regulations and security requirements of the Company concerning the safety of persons and property.

6 Proprietary Information and Inventions.

6.1 Proprietary Information.

(a) The Advisor acknowledges that the Advisor's relationship with the Company is one of high trust and confidence and that in the course of the Advisor's service to the Company, the Advisor will have access to and contact with Proprietary Information (as defined below). The Advisor will not disclose any Proprietary Information to any person or entity other than employees of the Company or use the same for any purposes (other than in the performance of the Services) without written approval by an officer of the Company, either during or after the Advisory Period, unless and until such Proprietary Information has become public knowledge without fault by the Advisor.

(b) For purposes of this Agreement, "**Proprietary Information**" shall mean, by way of illustration and not limitation, all information, whether or not in writing, whether or not patentable and whether or not copyrightable, of a private, secret or confidential nature, owned, possessed or used by the Company, concerning the Company's business, business relationships or financial affairs, including, without limitation, any Invention (as defined below), formula, vendor information, customer information, apparatus, equipment, trade secret, process, research, report, technical or research data, clinical data, know-how, computer program, software, software documentation, hardware design, technology, product, processes, methods, techniques, formulas, compounds, projects, developments, marketing or business plan, forecast, unpublished financial statement, budget, license, price, cost, customer, supplier or personnel information or employee list that is communicated to, learned of, developed or otherwise acquired by the Advisor in the course of Advisor's service as an Advisor to the Company.

(c) The Advisor agrees that all files, documents, letters, memoranda, reports, records, data sketches, drawings, models, laboratory notebooks, program listings, computer equipment or devices, computer programs or other written, photographic, or other tangible material containing Proprietary Information, whether created by the Advisor or others, which shall come into the Advisor's custody or possession, shall be and are the exclusive property of the Company to be used by the Advisor only in the performance of the Services and shall not be copied or removed from the Company's premises

except in the pursuit of the business of the Company. All such materials or copies thereof and all tangible property of the Company in the custody or possession of the Advisor shall be delivered to the Company, upon the earlier of (i) a request by the Company or (ii) the termination of this Agreement. After such delivery, the Advisor shall not retain any such materials or copies thereof or any such tangible property.

(d) The Advisor agrees that the Advisor's obligation not to disclose or to use information and materials of the types set forth in paragraphs (b) and (c) above, and the Advisor's obligation to return materials and tangible property set forth in paragraph (c) above extends to such types of information, materials and tangible property of customers of the Company or suppliers to the Company or other third parties who may have disclosed or entrusted the same to the Company or to the Advisor.

(e) The Advisor acknowledges that the Company from time to time may have agreements with other persons or with the United States Government, or agencies thereof, that impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. The Advisor agrees to be bound by all such obligations and restrictions that are known to the Advisor and to take all action necessary to discharge the obligations of the Company under such agreements.

(f) The Advisor's obligations under this Section 6.1 shall not apply to any information that (i) is or becomes known to the general public under circumstances involving no breach by the Advisor or others of the terms of this Section 6.1, (ii) is generally disclosed to third parties by the Company without restriction on such third parties, or (iii) is approved for release by written authorization of an officer of the Company. Further, nothing herein prohibits or restricts the Advisor from communicating with, or voluntarily providing information the Advisor believes indicates possible or actual violations of the law to, local, state or federal government agencies, any legislative body, law enforcement, or any self-regulatory organization (including but not limited to the Securities & Exchange Commission). The Advisor is not required to notify the Company of any such communications. In addition, notwithstanding the Advisor's confidentiality and nondisclosure obligations, the Advisor is hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

6.2 Inventions.

(a) All inventions, ideas, creations, discoveries, computer programs, works of authorship, data, developments, technology, designs, innovations and improvements (whether or not patentable and whether or not copyrightable) which are made, conceived, reduced to practice, created, written, designed or developed by the Advisor, solely or jointly with others or under Advisor's direction and whether during normal business hours or otherwise, (i) during the Advisory Period if related to the business of the Company or (ii) after the Advisory Period if derived from Proprietary Information (collectively under clauses (i) and (ii), "**Inventions**"), shall be the sole property of the Company. The Advisor hereby assigns to the Company all Inventions and any and all related patents, copyrights, trademarks, trade names, and other industrial and intellectual property rights and applications therefor, in the United States and elsewhere and appoints any officer of the Company as Advisor's duly authorized

attorney to execute, file, prosecute and protect the same before any government agency, court or authority. However, this paragraph shall not apply to Inventions which do not relate to the business or research and development conducted or planned to be conducted by the Company at the time such Invention is created, made, conceived or reduced to practice and which are made and conceived by the Advisor not during normal working hours, not on the Company's premises and not using the Company's tools, devices, equipment or Proprietary Information. The Advisor further acknowledges that each original work of authorship which is made by the Advisor (solely or jointly with others) within the scope of the Agreement and which is protectable by copyright is a "work made for hire," as that term is defined in the United States Copyright Act.

(b) The Advisor agrees that if, in the course of performing the Services, the Advisor incorporates into any Invention developed under this Agreement any preexisting invention, improvement, development, concept, discovery or other proprietary information owned by the Advisor or in which the Advisor has an interest ("**Prior Inventions**"), (i) the Advisor will inform the Company, in writing before incorporating such Prior Inventions into any Invention, and (ii) the Company is hereby granted a nonexclusive, royalty-free, perpetual, irrevocable, transferable worldwide license with the right to grant and authorize sublicenses, to make, have made, modify, use, import, offer for sale, sell, reproduce, distribute, modify, adapt, prepare derivative works of, display, perform, and otherwise exploit such Prior Inventions, without restriction, including, without limitation, as part of or in connection with such Invention, and to practice any method related thereto. The Advisor will not incorporate any invention, improvement, development, concept, discovery or other proprietary information owned by any third party into any Invention without the Company's prior written permission.

(c) Upon the request of the Company and at the Company's expense, the Advisor shall execute such further assignments, documents and other instruments as may be necessary or desirable to fully and completely assign all Inventions to the Company and to assist the Company in applying for, obtaining and enforcing patents or copyrights or other rights in the United States and in any foreign country with respect to any Invention. The Advisor also hereby waives all claims to moral rights in any Inventions.

(d) The Advisor shall promptly disclose to the Company all Inventions and will maintain adequate and current written records (in the form of notes, sketches, drawings and as may be specified by the Company) to document the conception and/or first actual reduction to practice of any Invention. Such written records shall be available to and remain the sole property of the Company at all times.

7 Exclusivity. The Company retains the right to contract with other companies and/or individuals for consulting services without restriction. Similarly, the Advisor retains the right to contract with other companies or entities for the Advisor's consulting services, subject to the Advisor's continued obligations to the Company, including as set forth in the Confidentiality Agreement and Separation Agreement.

8 Other Agreements; Warranty.

8.1 The Advisor hereby represents that, except as the Advisor has disclosed in writing to the Company, the Advisor is not bound by the terms of any agreement with any third party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of the Advisor's consultancy with the Company, to refrain from competing, directly or indirectly, with the business of such third party or to refrain from soliciting employees, customers or suppliers of such third party. The Advisor further represents that the Advisor's performance of all the terms of this Agreement and the performance of the Services do not and will not breach any agreement with any third party to

which the Advisor is a party (including, without limitation, any nondisclosure or non-competition agreement), and that the Advisor will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any current or previous employer or others.

8.2 The Advisor hereby represents, warrants and covenants that the Advisor has the skills and experience necessary to perform the Services, that Advisor will perform said Services in a professional, competent and timely manner, that the Advisor has the power to enter into this Agreement and that the Advisor's performance hereunder will not infringe upon or violate the rights of any third party or violate any federal, state or municipal laws.

9 Independent Contractor Status.

9.1 The Advisor shall perform all services under this Agreement as an "independent contractor" and not as an employee or agent of the Company. The Advisor is not authorized to assume or create any obligation or responsibility, express or implied, on behalf of, or in the name of, the Company or to bind the Company in any manner.

9.2 The Advisor shall have the right to control and determine the time, place, methods, manner and means of performing the Services. In performing the Services, the amount of time devoted by the Advisor on any given day will be entirely within the Advisor's control, and the Company will rely on the Advisor to put in the amount of time necessary to fulfill the requirements of this Agreement.

9.3 In the performance of the Services, the Advisor has the authority to control and direct the performance of the details of the Services, the Company being interested only in the results obtained. However, the Services contemplated by this Agreement must meet the Company's standards and approval and shall be subject to the Company's general right of inspection to secure their satisfactory completion.

9.4 The Advisor shall not use the Company's trade names, trademarks, service names or service marks without the prior approval of the Company.

9.5 The Advisor shall be solely responsible for all state and federal income taxes, unemployment insurance and social security taxes and for maintaining adequate workers' compensation insurance coverage.

10 Remedies. The Advisor acknowledges that any breach of the provisions of Sections 6 or 7 of this Agreement shall result in serious and irreparable injury to the Company for which the Company cannot be adequately compensated by monetary damages alone. The Advisor agrees, therefore, that, in addition to any other remedy the Company may have, the Company shall be entitled to enforce the specific performance of this Agreement by the Advisor and to seek both temporary and permanent injunctive relief (to the extent permitted by law) without the necessity of proving actual damages or posting a bond.

11 Notices. All notices required or permitted under this Agreement shall be in writing and will be either personally delivered, sent by reputable overnight courier service, mailed by first class mail, or sent via e-mail with a subject header that includes the word "Notice".

12 Pronouns. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns and pronouns shall include the plural, and vice versa.

13 Entire Agreement. This Agreement constitutes the entire agreement between the parties relating to the subject matter of this Agreement, and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement.

14 Amendment and Waiver. This Agreement may be amended, waived, or modified only by a written instrument executed by both the Company and the Advisor.

15 Non-Assignability of Contract. This Agreement is personal to the Advisor and the Advisor shall not have the right to assign any of the Advisor's rights or delegate any of the Advisor's duties without the express written consent of the Company. Any non-consented-to assignment or delegation, whether express or implied or by operation of law, shall be void.

16 Governing Law; Forum. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without giving effect to any choice or conflict of law provision or rule that would cause the application of laws of any other jurisdiction. Any action, suit or other legal proceeding arising out of, under or in connection with this Agreement shall be subject to arbitration in accordance with Section 11 of the Confidentiality Agreement.

17 Successors and Assigns. This Agreement shall be binding upon, and inure to the benefit of, both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to its assets or business; provided, however, that the obligations of the Advisor are personal and shall not be assigned by the Advisor.

18 Interpretation. If any restriction set forth in Section 6 is found by an arbitrator or any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range of activities or geographic area as to which it may be enforceable.

19 Survival. Sections 4 through 20 shall survive the termination of this Agreement.

20 Miscellaneous.

20.1 No delay or omission by either of the parties in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by either of the parties on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

20.2 The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

20.3 In the event that any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

[*Remainder of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, the parties hereto have executed this Advisor Agreement as of the date and year first above written.

COMPANY:

VERVE THERAPEUTICS, INC.

By: /s/ Andrew D. Ashe
Andrew D. Ashe
Chief Operating Officer & General Counsel

ADVISOR:

/s/ Andrew Bellinger
Andrew Bellinger

Exhibit 31.1

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) 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

   (d) 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: August 8, 2024

By: /s/ Sekar Kathiresan

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

Exhibit 31.2

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) 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

   (d) 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: August 8, 2024

By: /s/ Allison Dorval

Allison Dorval
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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 ended June 30, 2024 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, to my knowledge:

(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: August 8, 2024

By: /s/ Sekar Kathiresan
Sekar Kathiresan, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 ended June 30, 2024 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, to my knowledge:

(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: August 8, 2024

By: /s/ Allison Dorval
Allison Dorval
Chief Financial Officer
(Principal Financial Officer)