

REFINITIV

DELTA REPORT

10-Q

VERV - VERVE THERAPEUTICS, INC.

10-Q - SEPTEMBER 30, 2023 COMPARED TO 10-Q - JUNE 30, 2023

The following comparison report has been automatically generated

| | |
|--------------|------|
| TOTAL DELTAS | 4805 |
|--------------|------|

| | |
|---|-----|
|  CHANGES | 203 |
|---|-----|

| | |
|---|------|
|  DELETIONS | 4105 |
|---|------|

| | |
|---|-----|
|  ADDITIONS | 497 |
|---|-----|

**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** **September** 30, 2023

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

(State or other jurisdiction of
incorporation or organization)

82-4800132

(I.R.S. Employer
Identification No.)

201 Brookline Avenue, Suite 601

Boston, Massachusetts

(Address of principal executive offices)

02215

(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 | Name of each exchange on which registered |
|---------------------|-----------|---|
| | Symbol(s) | |

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 3, 2023 October 31, 2023 the registrant had 63,721,263 63,752,748 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 initiation, timing, progress and results of our research and development programs, preclinical studies and clinical trials including the timing of our submissions of investigational new drug, or IND, applications, and clinical trial applications to regulatory authorities;
- the timing and conduct of our heart-1 clinical trial, an ongoing Phase 1b clinical trial of VERVE-101, including statements regarding the activation of clinical trial sites in the United States, the timing of enrollment and completion of the clinical trials and the period during which the data from clinical trials will become available;
- our expectations related to the hold that the U.S. Food and Drug Administration, or FDA, placed on our IND to conduct a clinical trial evaluating VERVE-101 in the United States;
- 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 Beam Therapeutics Inc., Vertex Pharmaceuticals Incorporated and Eli Lilly and Company; and
- the potential impact of public health epidemics or pandemics, including the COVID-19 pandemic, and of global economic developments, including rising 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 very early in our development efforts, and we only initiated our first clinical trial of a product candidate, VERVE-101, our lead product candidate targeting *PCSK9*, in 2022. As a result, we expect it will be many years before we commercialize any product candidate, if ever. If we are unable to advance our current or future product candidates into and through clinical trials, obtain marketing approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed;

- The U.S. Food and Drug Administration has placed the investigational new drug, or IND, application to conduct a clinical trial evaluating VERVE-101 in the United States on hold. We cannot be certain that the hold will be lifted on a timely basis, or at all, and we may not be able to initiate our clinical trial of VERVE-101 in the United States;
- Gene editing, including base editing, is a novel technology in a rapidly evolving field that is not yet clinically validated as being safe and efficacious for human therapeutic use. The approaches we are taking to discover and develop novel therapeutics are unproven and may never lead to marketable products. We are focusing our research and development efforts for VERVE-101, VERVE-102, our product candidate targeting *PCSK9* using our GalNAc-LNP delivery technology, and VERVE-201, our product candidate targeting *ANGPTL3*, on gene editing using base editing technology, but other gene editing technologies may be discovered that provide significant advantages over base editing and we may not be able to access or use those technologies, which could materially harm our business. We are also seeking to discover 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 preliminary top-line data from our clinical trials may materially change as participant enrollment continues, and more participant data become available and audit and verification procedures are conducted. As a result, preliminary, interim or top-line data should be viewed with caution until the final data are available;
- If any of the product candidates we may 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 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 license arrangements with third parties, or otherwise

experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business;

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

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Part I □ Financial Information

Item 1. Financial Statements

Verve Therapeutics, Inc.

Condensed consolidated balance sheets

| (in thousands, except share and per share amounts) (unaudited) | June 30, 2023 | Decemb er 31, 2022 | Septem ber 30, 2023 | Decemb er 31, 2022 |
|---|---------------------|--------------------------|---------------------------|--------------------------|
| Assets | | | | |
| Current assets: | | | | |
| Cash and cash equivalents | 70,0 \$ 42 | 115,4 \$ 12 | 78,37 \$ 0 | 115,4 \$ 12 |
| Marketable securities | 392, 434 | 439,3 96 | 406,8 56 | 439,3 96 |
| Collaboration receivable | 2,09 3 | 1,012 | 3,145 | 1,012 |
| Prepaid expenses and other current assets | 8,49 7 | 7,339 | 9,890 | 7,339 |
| Total current assets | 473, 066 | 563,1 59 | 498,2 61 | 563,1 59 |
| Property and equipment, net | 21,2 52 | 18,77 8 | 20,80 3 | 18,77 8 |
| Restricted cash | 4,82 4 | 4,824 | 4,774 | 4,824 |
| Operating lease right-of-use assets | 88,7 66 | 91,87 7 | 87,04 1 | 91,87 7 |
| Other long term assets | 1,22 3 | 585 | 1,528 | 585 |
| Total assets | 589, \$ 131 | 679,2 \$ 23 | 612,4 \$ 07 | 679,2 \$ 23 |
| Liabilities and stockholders' equity | | | | |
| Current liabilities: | | | | |
| Accounts payable | 3,14 \$ 6 | 2,424 | \$ 1,054 | \$ 2,424 |

| | | | | |
|---|--------|-------|--------|-------|
| Accrued expenses | 19,8 | 20,76 | 23,40 | 20,76 |
| | 39 | 7 | 3 | 7 |
| Lease liability, current portion | 10,0 | 11,90 | 10,11 | 11,90 |
| | 46 | 4 | 8 | 4 |
| Total current liabilities | 33,0 | 35,09 | 34,57 | 35,09 |
| | 31 | 5 | 5 | 5 |
| Long term lease liability | 67,8 | 70,01 | 66,68 | 70,01 |
| | 19 | 4 | 9 | 4 |
| Success payment liability | 2,80 | | | |
| | 9 | 2,885 | 2,007 | 2,885 |
| Deferred revenue, non-current | 20,0 | 20,01 | 48,55 | 20,01 |
| | 14 | 4 | 4 | 4 |
| Other long term liabilities | 236 | 283 | 213 | 283 |
| Total liabilities | 123, | 128,2 | 152,0 | 128,2 |
| | 909 | 91 | 38 | 91 |
| 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, 62,064,279 and 61,730,816 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively | 62 | 62 | | |
| Common stock, \$0.001 par value; 200,000,000 shares authorized, 63,737,089 and 61,730,816 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively | | | 64 | 62 |
| Additional paid-in capital | 916, | 895,8 | 956,8 | 895,8 |
| | 109 | 01 | 55 | 01 |
| Accumulated other comprehensive loss | (754) | (694) | (597) | (694) |
| Accumulated deficit | (450 | (344, | (495,9 | (344, |
| | ,195) | 237) | 53) | 237) |
| Total stockholders' equity | 465, | 550,9 | 460,3 | 550,9 |
| | 222 | 32 | 69 | 32 |
| Total liabilities and stockholders' equity | 589, | 679,2 | 612,4 | 679,2 |
| | \$ 131 | \$ 23 | \$ 07 | \$ 23 |

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

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

| | Three months ended June 30, | | Six months ended June 30, | | Three months ended September 30, | | Nine months ended September 30, | |
|--|-----------------------------|------|---------------------------|------|----------------------------------|--------|---------------------------------|--------|
| (in thousands, except share and per share amounts) (unaudited) | 2023 | 2022 | 2023 | 2022 | 2023 | 2022 | 2023 | 2022 |
| Collaboration revenue | 2,09 | | 3,4 | | 3,11 | | 6,61 | |
| | \$ 3 | \$ — | \$ 97 | \$ — | \$ 7 | \$ 929 | \$ 4 | \$ 929 |
| Operating expenses: | | | | | | | | |
| Research and development | 47,2 | 33,1 | 94, | 57,6 | 43,7 | 35,1 | 138, | 92,8 |
| | 60 | 25 | 370 | 14 | 65 | 97 | 135 | 11 |
| General and administrative | 13,4 | 9,06 | 25, | 16,5 | 11,6 | 9,59 | 37,6 | 26,0 |
| | 16 | 7 | 969 | 03 | 86 | 2 | 55 | 95 |
| Total operating expenses | 60,6 | 42,1 | ,33 | 74,1 | 55,4 | 44,7 | 175, | 118, |
| | 76 | 92 | 9 | 17 | 51 | 89 | 790 | 906 |
| Loss from operations | | | (11 | | | | | |
| | (58, | (42, | 6,8 | (74, | (52,3 | (43,8 | (169 | (117, |
| | 583) | 192) | 42) | 117) | 34) | 60) | ,176) | 977) |
| Other income: | | | | | | | | |
| Other income (expense): | | | | | | | | |

| | | | | | | | | |
|---|------------|------------|------------|------------|------------|------------|------------|------------|
| Change in fair value of success payment liability | | | | 2,615 | | (3,306) | | |
| Interest and other income, net | 5,438 | 308 | 10,984 | 390 | 5,841 | 1,976 | 16,825 | 2,366 |
| Total other income, net | 4,776 | 1,246 | 11,060 | 3,005 | | | | |
| Total other income (expense), net | | | | | 6,643 | (1,330) | 17,703 | 1,675 |
| Loss before provision for income taxes | (53,807) | (40,946) | (10,578) | (71,112) | (45,691) | (45,190) | (151,473) | (116,302) |
| Provision for income taxes | (176) | - | (176) | - | (67) | - | (243) | - |
| Net loss | (53,983) | (40,946) | (10,595) | (71,112) | (45,758) | (45,190) | (151,716) | (116,302) |
| Net loss per common share, basic and diluted | (0.87) | (0.84) | (1.71) | (1.46) | (0.72) | (0.79) | (2.43) | (2.26) |
| Weighted-average common shares used in net loss | 61,953,992 | 48,674,873 | 61,871,158 | 48,623,330 | 63,211,849 | 57,207,125 | 62,322,965 | 51,516,037 |
| Comprehensive Loss: | | | | | | | | |
| Comprehensive loss: | | | | | | | | |
| Net loss | (53,983) | (40,946) | (10,595) | (71,112) | (45,758) | (45,190) | (151,716) | (116,302) |

| | | | | | | | | |
|---|--------------|--------------|-------------|--------------|--------------|--------------|---------------|---------------|
| Other comprehensive loss: | | | | | | | | |
| Unrealized loss on marketable securities | (517) | (206) | (60) | (710) | | | | |
| Unrealized gain (loss) on marketable securities | | | | | 157 | 18 | 97 | (692) |
| Comprehensive loss | (54, \$ 500) | (41, \$ 152) | (6,0 \$ 18) | (71, \$ 822) | (45,6 \$ 01) | (45,1 \$ 72) | (151 \$,619) | (116, \$ 994) |

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 | | | | | | Common stock | | | | | |
|---|--------------|-------|--------|-------|--------|-------|--------------|-------|--------|-------|--------|-------|
| | | | Additi | | Accu | Total | | | Additi | | Accu | Total |
| | | | onal | | mulat | stock | | | onal | | mulat | stock |
| | Shar | Amou | paid- | other | Accu | hold | Shar | Amou | paid- | other | Accu | hold |
| | es | nt | in | rehe | mulat | ers' | es | nt | in | rehe | mulat | ers' |
| | es | nt | capita | nsive | defici | equit | es | nt | capita | nsive | defici | equit |
| | | | l | loss | t | y | | | l | loss | t | y |
| Balance at | 48, | | | | | 35 | 48, | | | | | 35 |
| December 31, | 51 | | 54 | | (18 | 7, | 51 | | 54 | | (18 | 7, |
| 2021 | 1,7 | | 4,3 | (22 | 6,8 | 35 | 1,7 | | 4,3 | (22 | 6,8 | 35 |
| | 35 | \$ 49 | \$ 81 | \$ 8) | \$ 50) | \$ 2 | 35 | \$ 49 | \$ 81 | \$ 8) | \$ 50) | \$ 2 |

| | | | | | | | | | | | | |
|---|-----|----|-----|-----|-----|------|-----|----|-----|-----|-----|-----|
| Exercise of stock options | 14 | | | | | | 14 | | | | | |
| | 3,5 | | 50 | | | 50 | 3,5 | | 50 | | | 50 |
| | 06 | — | 5 | — | — | 5 | 06 | — | 5 | — | — | 5 |
| Unrealized loss on marketable securities | | | | (50 | | (5 | | | | (50 | | (5 |
| | — | — | — | 4) | — | 04) | — | — | — | 4) | — | 04) |
| Stock-based compensation | | | | | | 4, | | | | | | 4, |
| | — | — | 4,2 | | | 20 | | | 4,2 | | | 20 |
| | — | — | 03 | — | — | 3 | — | — | 03 | — | — | 3 |
| Net loss | | | | | | (3 | | | | | | (3 |
| | | | | | (30 | 0, | | | | | (30 | 0, |
| | | | | | ,16 | 16 | | | | | ,16 | 16 |
| | — | — | — | — | 6) | 6) | — | — | — | — | 6) | 6) |
| Balance at March 31, 2022 | 48, | | | | | 33 | 48, | | | | | 33 |
| | 65 | | 54 | | (21 | 1, | 65 | | 54 | | (21 | 1, |
| | 5,2 | | 9,0 | (73 | 7,0 | 39 | 5,2 | | 9,0 | (73 | 7,0 | 39 |
| | 41 | 49 | 89 | 2) | 16) | 0 | 41 | 49 | 89 | 2) | 16) | 0 |
| Exercise of stock options | 29, | | | | | | 29, | | | | | |
| | 19 | | 12 | | | 12 | 19 | | 12 | | | 12 |
| | 3 | — | 0 | — | — | \$ 0 | 3 | — | 0 | — | — | 0 |
| Issuance of common stock under employee stock purchase plan | 25, | | | | | | 25, | | | | | |
| | 21 | | 32 | | | 32 | 21 | | 32 | | | 32 |
| | 8 | — | 5 | — | — | 5 | 8 | — | 5 | — | — | 5 |
| Unrealized loss on marketable securities | | | | (20 | | (2 | | | | (20 | | (2 |
| | — | — | — | 6) | — | 06) | — | — | — | 6) | — | 06) |
| Stock-based compensation | | | | | | 5, | | | | | | 5, |
| | — | — | 5,6 | | | 65 | | | 5,6 | | | 65 |
| | — | — | 50 | — | — | 0 | — | — | 50 | — | — | 0 |

| | | | | | | | | | | | | |
|--|------------|---|---|----|----|----------|------------|---|---|--------|----|----------|
| Net loss | (40,946) | | | | | | (40,946) | | | | | |
| | — | — | — | — | 6) | 6) | — | — | — | — | 6) | 6) |
| Balance at June 30, 2022 | 48,709,652 | | | 55 | | (25,633) | 48,709,652 | | | 55 | | (25,633) |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| Exercise of stock options | | | | | | | 41,350 | | | | | 1,110 |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| Issuance of common stock in connection with the Vertex Agreement | | | | | | | 1,519,756 | | | 39,985 | | 39,987 |
| | | | | | | | | | | | | |
| Issuance of common stock from follow-on public offering, net of issuance costs of \$15.9 million | | | | | | | 9,583,334 | | | 24,283 | | 24,884 |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| Issuance of common stock from At-the-Market offering, net of issuance costs of \$0.6 million | | | | | | | 21,693 | | | 6,920 | | 6,920 |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| Unrealized gain on marketable securities | | | | | | | — | | | - | 18 | - |
| | | | | | | | | | | | | |

[illegible]

| | | | | | | | | | | | | |
|---|-------|-------|-------|-------|--------|------|-------|----|----|----|-----|-----|
| Net loss | (5 | | | | | | (5 | | | | | |
| | (51 | | | | | | (51 | | | | | |
| | ,97 | | | | | | ,97 | | | | | |
| | — | — | — | — | 5) | 5) | — | — | — | — | 5) | 5) |
| Balance at March 31, 2023 | 61,50 | | | | | | 61,50 | | | | | |
| | 86 | | | | | | 86 | | | | | |
| | 90 | | | | | | 90 | | | | | |
| | (39 | | | | | | (39 | | | | | |
| | 6,2 | | | | | | 6,2 | | | | | |
| | 47 | | | | | | 47 | | | | | |
| | 10 | 62 | 63 | 7) | 12) | 6 | 10 | 62 | 63 | 7) | 12) | 6 |
| Exercise of stock options | 98,59 | | | | | | 98,59 | | | | | |
| | 54 | | | | | | 54 | | | | | |
| | 8 | - | 8 | - | - | 8 | 8 | - | 8 | - | - | 8 |
| Vesting of restricted stock units | 50,53 | | | | | | 50,53 | | | | | |
| | 7 | - | - | - | - | - | 7 | - | - | - | - | - |
| Issuance of common stock under employee stock purchase plan | 52,13 | | | | | | 52,13 | | | | | |
| | 68 | | | | | | 68 | | | | | |
| | 4 | - | 5 | - | - | 5 | 4 | - | 5 | - | - | 5 |
| Unrealized loss on marketable securities | (51 | | | | | | (51 | | | | | |
| | 7) | | | | | | 7) | | | | | |
| | - | - | - | - | - | 17) | - | - | - | - | - | 17) |
| Stock-based compensation | 9,01 | | | | | | 9,01 | | | | | |
| | - | - | 13 | - | - | 3 | - | - | 13 | - | - | 3 |
| Net loss | (5 | | | | | | (5 | | | | | |
| | (53 | | | | | | (53 | | | | | |
| | ,98 | | | | | | ,98 | | | | | |
| | - | - | - | - | 3) | 3) | - | - | - | - | 3) | 3) |
| Balance at June 30, 2023 | 62,46 | | | | | | 62,46 | | | | | |
| | 06 | | | | | | 06 | | | | | |
| | 91 | | | | | | 91 | | | | | |
| | (45 | | | | | | (45 | | | | | |
| | 0,1 | | | | | | 0,1 | | | | | |
| | 22 | | | | | | 22 | | | | | |
| | 79 | \$ 62 | \$ 09 | \$ 4) | \$ 95) | \$ 2 | 79 | 62 | 09 | 4) | 95) | 2 |

| | | | | | | | |
|----------------|-----|-------|-------|-------|--------|--|------|
| Exercise of | 43, | | | | | | |
| stock options | 42 | | 21 | | | | 21 |
| | 9 | - | 3 | - | - | | 3 |
| Vesting of | 76, | | | | | | |
| restricted | 58 | | | | | | |
| stock units | 6 | - | - | | | | - |
| Issuance of | | | | | | | |
| common stock | 1,5 | | | | | | |
| in connection | 52, | | 31, | | | | 31 |
| with the Lilly | 79 | | 70 | | | | ,7 |
| Agreement | 5 | 2 | 8 | | | | 10 |
| Unrealized | | | | | | | |
| gain on | | | | | | | |
| marketable | | | | | 15 | | 15 |
| securities | - | - | - | 7 | - | | 7 |
| Stock-based | | | | | | | 8, |
| compensation | | | 8,8 | | | | 82 |
| | - | - | 25 | - | - | | 5 |
| Net loss | | | | | | | (4 |
| | | | | | (45 | | 5, |
| | | | | | ,75 | | 75 |
| | - | - | - | - | 8) | | 8) |
| Balance at | 63, | | | | | | 46 |
| September 30, | 73 | | 95 | | (49 | | 0, |
| 2023 | 7,0 | | 6,8 | (59 | 5,9 | | 36 |
| | 89 | \$ 64 | \$ 55 | \$ 7) | \$ 53) | | \$ 9 |

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

Verve Therapeutics, Inc. Condensed consolidated statements of cash flows

| | Six months ended June 30, | Nine months ended September 30, |
|--|---------------------------|---------------------------------|
|--|---------------------------|---------------------------------|

| (unaudited, in thousands) | 2023 | 2022 | 2023 | 2022 |
|--|-----------|----------|-----------|-----------|
| Cash flows from operating activities: | | | | |
| Net loss | (105,958) | (71,112) | (151,716) | (116,302) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Depreciation | 2,464 | 1,162 | 3,938 | 1,879 |
| Non-cash lease expense | 3,321 | 999 | 5,046 | 2,279 |
| Net amortization of premium (accretion of discount) on marketable securities | (7,551) | 1,231 | (11,044) | 1,114 |
| Stock-based compensation | 17,037 | 9,853 | 25,862 | 15,773 |
| Change in fair value of success payments liabilities | (76) | (2,615) | (878) | 691 |
| Changes in operating assets and liabilities: | | | | |
| Collaboration receivable | | | (3,117) | (929) |
| Prepaid expenses and other assets | (2,955) | (2,894) | (2,587) | (9,368) |
| Accounts payable | 1,471 | (1,017) | (589) | (6,411) |
| Accrued expenses and other liabilities | (549) | 5,176 | 2,996 | 4,661 |
| Operating lease liabilities | (4,262) | (1,048) | (5,320) | (2,841) |
| Deferred revenue | | | 28,540 | 20,014 |
| Net cash used in operating activities | (97,058) | (60,265) | (108,869) | (89,440) |
| Cash flows from investing activities: | | | | |
| Purchases of property and equipment | (6,037) | (5,627) | (7,098) | (8,264) |
| Purchases of marketable securities | (246,877) | (74,249) | (394,817) | (222,078) |
| Maturities of marketable securities | 301,331 | 147,750 | 438,498 | 242,700 |
| Net cash provided by investing activities | 48,417 | 67,874 | 36,583 | 12,358 |
| Cash flows from financing activities: | | | | |
| Proceeds from issuance of common stock, net of issuance costs | 1,922 | - | | |
| Proceeds from the issuance of common stock in connection with collaboration agreements | | | 31,710 | 39,986 |
| Proceeds from issuance of common stock, net of commissions | | | 1,987 | 247,919 |

| | | | | |
|--|-----------|-----------|-----------|------------|
| Payment of equity offering costs | | | (65) | (605) |
| Proceeds from exercise of stock options | 664 | 625 | 877 | 1,733 |
| Issuance of common stock under employee stock purchase plan | 685 | 325 | 685 | 325 |
| Net cash provided by financing activities | 3,271 | 950 | 35,194 | 289,358 |
| Increase (decrease) in cash, cash equivalents and restricted cash | (45,370) | 8,559 | (37,092) | 212,276 |
| Cash, cash equivalents and restricted cash—beginning of period | 120,236 | 69,567 | 120,236 | 69,567 |
| Cash, cash equivalents and restricted cash—end of period | \$ 74,866 | \$ 78,126 | \$ 83,144 | \$ 281,843 |
| Supplemental disclosure of noncash investing and financing activities: | | | | |
| Property and equipment additions included in accounts payable and accrued expenses | \$ 532 | \$ 1,169 | \$ 495 | \$ 2,025 |
| Offering costs included in accounts payable and accrued liabilities | | | \$ — | \$ 175 |
| Right-of-use assets obtained in exchange for new operating lease liabilities | | | \$ — | \$ 81,244 |

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

Liquidity and capital resources

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

In June 2023, the Company entered into a Research and Collaboration Agreement (the "Lilly Agreement") with Eli Lilly and Company ("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, as further described in Note 15, "Subsequent events." The Lilly Agreement became effective in July 2023 upon the expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended ("HSR Clearance"). Pursuant to the Lilly Agreement, Verve received the upfront payment of \$30.0 million from Lilly in August 2023. The Company is eligible to receive up to an aggregate of \$465 million in research, development and commercial milestone payments and tiered and incremental high single and low-double digit royalties on global net sales, subject to specified reductions.

In June 2023, in connection with the execution of the Lilly Agreement, the Company also entered into a stock purchase agreement with Lilly (the "Lilly Stock Purchase Agreement") for the sale and issuance of 1,552,795 shares of the Company's common stock to Lilly at a price of \$19.32 per share, which was equal to a 15% premium to the volume-weighted average share price of its common stock over the 30 trading days prior to June 14, 2023, for an aggregate purchase price of \$30.0 million (the "Private Placement"). The Private Placement closed on July 31, 2023.

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 \$462.5 million as of June 30, 2023 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

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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, 2023 September 30, 2023, the results of its operations and other comprehensive loss for the three and six nine months ended June 30, 2023 September 30, 2023 and 2022, stockholders' equity for the three and six nine months ended June 30, 2023 September 30, 2023 and 2022 and cash flows for the six nine months ended June 30, 2023 September 30, 2023 and 2022. Such adjustments are of a normal and recurring nature. The results for the three and six nine months ended June 30, 2023 September 30, 2023 are not necessarily indicative of the results for the year ending December 31, 2023, 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, 2022,

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December 31, 2022, and the notes thereto, included in the Company's Annual Report on Form 10-K filed with the SEC on March 2, 2023.

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, 2022, and notes thereto, included in the Company's Annual Report on Form 10-K filed with the SEC on March 2, 2023. 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, 2023 | June 30, 2022 | September 30, 2023 | September 30, 2022 |
|----------------|------------------|------------------|-----------------------|-----------------------|
|----------------|------------------|------------------|-----------------------|-----------------------|

| | | | | |
|--|-----------|-----------|-----------|------------|
| Cash and cash equivalents | \$ 70,042 | \$ 72,889 | \$ 78,370 | \$ 277,019 |
| Restricted cash | 4,824 | 5,237 | 4,774 | 4,824 |
| Total cash, cash equivalents and restricted cash | \$ 74,866 | \$ 78,126 | \$ 83,144 | \$ 281,843 |

Recently adopted accounting pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that was previously used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, this standard requires allowances to be recorded instead of reducing the amortized cost of the investment. The Company adopted the new standard on January 1, 2023. Based upon the Company's analysis, the adoption of this new standard did not have a material impact on the Company's financial statements.

3. Marketable securities

Marketable securities by security type consisted of the following:

| | June 30, 2023 | | | |
|-------------------------------|----------------|------------------------|-------------------------|------------|
| (in thousands) | Amortized cost | Gross unrealized gains | Gross unrealized losses | Fair value |
| U.S. treasury bills and notes | \$ 189,166 | \$ 6 | \$ (454) | \$ 188,718 |
| U.S. agency securities | 204,022 | 39 | (345) | 203,716 |
| Total | \$ 393,188 | \$ 45 | \$ (799) | \$ 392,434 |

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| | September 30, 2023 | | | |
|-------------------------------|--------------------|------------------------|-------------------------|------------|
| (in thousands) | Amortized cost | Gross unrealized gains | Gross unrealized losses | Fair value |
| U.S. treasury bills and notes | \$ 112,735 | \$ 2 | \$ (84) | \$ 112,653 |
| U.S. agency securities | 294,718 | 21 | (536) | 294,203 |
| Total | \$ 407,453 | \$ 23 | \$ (620) | \$ 406,856 |

| | December 31, 2022 | | | |
|----------------|-------------------|------------------------|-------------------------|------------|
| (in thousands) | Amortized cost | Gross unrealized gains | Gross unrealized losses | Fair value |

| | | | | | | | | |
|-------------------------------|----|---------|----|----|----|-------|----|---------|
| U.S. treasury bills and notes | \$ | 228,432 | \$ | 13 | \$ | (301) | \$ | 228,144 |
| U.S. agency securities | | 211,658 | | 68 | | (474) | | 211,252 |
| Total | \$ | 440,090 | \$ | 81 | \$ | (775) | \$ | 439,396 |

The remaining contractual maturities of all marketable securities were less than 12 15 months as of June 30, 2023 September 30, 2023 and 18 months as of December 31, 2022. The gross unrealized losses on the Company's marketable securities of \$0.6 million and \$0.8 million as of both June 30, 2023 September 30, 2023 and December 31, 2022, 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 does not consider those marketable securities to be impaired at June 30, 2023 September 30, 2023 or December 31, 2022. The Company has not recorded any allowance for credit losses. None of the

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Company's marketable securities have been in a continuous unrealized loss position for 12 months or greater as of June 30, 2023 September 30, 2023 or December 31, 2022.

4. Property and equipment, net

Property and equipment, net, consisted of the following:

| (in thousands) | December 31, | | September 30, | December 31, |
|-------------------------------|---------------|-----------|---------------|--------------|
| | June 30, 2023 | 2022 | 2023 | 2022 |
| Lab equipment | \$ 25,117 | \$ 20,379 | \$ 25,649 | \$ 20,379 |
| Leasehold improvements | 266 | 266 | 746 | 266 |
| Furniture and fixtures | 2,311 | 2,294 | 2,323 | 2,294 |
| Computer equipment | 969 | 826 | 970 | 826 |
| Total property and equipment | 28,663 | 23,765 | 29,688 | 23,765 |
| Less accumulated depreciation | (7,411) | (4,987) | (8,885) | (4,987) |
| Property and equipment, net | \$ 21,252 | \$ 18,778 | \$ 20,803 | \$ 18,778 |

The following table summarizes depreciation expense incurred:

| (in thousands) | Three months ended June 30, | | Six months ended June 30, | | Three months ended September 30, | | Nine months ended September 30, | |
|----------------------|-----------------------------|--------|---------------------------|------|----------------------------------|--------|---------------------------------|----------|
| | 2023 | 2022 | 2023 | 2022 | 2023 | 2022 | 2023 | 2022 |
| Depreciation expense | \$ 1,337 | \$ 648 | \$ 4 | \$ 2 | \$ 1,474 | \$ 717 | \$ 3,938 | \$ 1,879 |

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:

| (in thousands) | As of June 30, 2023 | | | |
|-------------------------------|---------------------|-----------|------------|----------|
| | Fair value | Level 1 | Level 2 | Level 3 |
| Assets | | | | |
| Money market funds | \$ 31,199 | \$ 31,199 | \$ — | \$ — |
| Marketable securities: | | | | |
| U.S. treasury bills and notes | 188,718 | — | 188,718 | — |
| U.S. agency securities | 203,716 | — | 203,716 | — |
| Total assets | \$ 423,633 | \$ 31,199 | \$ 392,434 | \$ — |
| Liabilities | | | | |
| Success payment liability | \$ 2,809 | \$ — | \$ — | \$ 2,809 |
| Total liabilities | \$ 2,809 | \$ — | \$ — | \$ 2,809 |

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| (in thousands) | As of September 30, 2023 | | | |
|----------------|--------------------------|---------|---------|---------|
| | Fair value | Level 1 | Level 2 | Level 3 |
| Assets | | | | |

| | | | | |
|-------------------------------|------------|-----------|------------|----------|
| Money market funds | \$ 57,567 | \$ 57,567 | \$ — | \$ — |
| Marketable securities: | | | | |
| U.S. treasury bills and notes | 112,653 | — | 112,653 | — |
| U.S. agency securities | 294,203 | — | 294,203 | — |
| Total assets | \$ 464,423 | \$ 57,567 | \$ 406,856 | \$ — |
| Liabilities | | | | |
| Success payment liability | \$ 2,007 | \$ — | \$ — | \$ 2,007 |
| Total liabilities | \$ 2,007 | \$ — | \$ — | \$ 2,007 |

| As of December 31, 2022 | | | | |
|-------------------------------|------------|------------|------------|----------|
| (in thousands) | Fair value | Level 1 | Level 2 | Level 3 |
| Assets | | | | |
| Money market funds | \$ 105,303 | \$ 105,303 | \$ — | \$ — |
| Marketable securities: | | | | |
| U.S. treasury bills and notes | 228,144 | — | 228,144 | — |
| U.S. agency securities | 211,252 | — | 211,252 | — |
| Total assets | \$ 544,699 | \$ 105,303 | \$ 439,396 | \$ — |
| Liabilities | | | | |
| Success payment liability | \$ 2,885 | \$ — | \$ — | \$ 2,885 |
| Total liabilities | \$ 2,885 | \$ — | \$ — | \$ 2,885 |

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Cash Equivalents—Cash equivalents of \$31.257.6 million and \$105.3 million as of June 30, 2023 September 30, 2023 and December 31, 2022, 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 high

nine-digit dollar amount to \$10.0 billion, or in the event of a 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 common stock, or a combination of cash and shares of 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 an increase decreases of \$0.7 0.8 million recorded to other expense and a decrease of \$0.1 0.9 million recorded to other income for the three and six nine months ended June 30, 2023 September 30, 2023, respectively, and decreases increases of \$0.9 3.3 million and \$2.6 0.7 million recorded to other income expense for the three and six nine months ended June 30, 2022 September 30, 2022, respectively.

The primary inputs used in valuing the success payment liability at June 30, 2023 September 30, 2023 and December 31, 2022, were as follows:

| | At June 30, 2023 | At December 31, 2022 | At September 30, 2023 | At December 31, 2022 |
|--|------------------------|----------------------------|-----------------------------|----------------------------|
| Fair value of common stock (per share) | \$ 18.75 | \$ 19.35 | \$ 13.26 | \$ 19.35 |
| Equity volatility | 80 % | 84 % | 84 % | 84 % |

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

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

| (in thousands) | Success payment |
|----------------|--------------------|
|----------------|--------------------|

| | | liability |
|-------------------------------|----|-----------|
| Balance at December 31, 2022 | \$ | 2,885 |
| Changes in fair value | | (878) |
| Balance at September 30, 2023 | \$ | 2,007 |

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

| (in thousands) | Success payment liability | Success payment liability |
|-------------------------------|---------------------------------|---------------------------------|
| Balance at December 31, 2021 | \$ 4,371 | \$ 4,371 |
| Changes in fair value | (2,615) | 691 |
| Balance at June 30, 2022 | \$ 1,756 | |
| Balance at September 30, 2022 | | \$ 5,062 |

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6. Accrued expenses

Accrued expenses consisted of the following:

| (in thousands) | June 30, 2023 | December 31, 2022 | September 30, 2023 | December 31, 2022 |
|--|------------------|-------------------------|--------------------------|-------------------------|
| Employee compensation and related benefits | \$ 6,347 | \$ 9,124 | \$ 9,322 | \$ 9,124 |
| Accrued external research and development expenses | 9,228 | 8,919 | 9,995 | 8,919 |
| Professional fees | 3,221 | 1,193 | 2,665 | 1,193 |
| License and milestone payments | 310 | 310 | 348 | 310 |
| Other | 733 | 1,221 | 1,073 | 1,221 |
| Total | \$ 19,839 | \$ 20,767 | \$ 23,403 | \$ 20,767 |

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 \$0.30.4 million and \$0.50.9 million of short term lease costs associated with the embedded leases during the three and six nine months ended June 30, 2023 September 30, 2023, respectively. The Company has recognized \$1.00.2 million and \$1.30.6 million of short term lease costs associated with the embedded leases during the three and six nine months ended June 30, 2022 September 30, 2022, respectively.

The components of operating lease cost were as follows:

| (in thousands) | Three months ended June 30, | | Six months ended June 30, | | Three months ended September 30, | | Nine months ended September 30, | |
|-----------------------|-----------------------------|--------|---------------------------|----------|----------------------------------|----------|---------------------------------|----------|
| | 2023 | 2022 | 2023 | 2022 | 2023 | 2022 | 2023 | 2022 |
| Operating lease costs | \$ 3,234 | \$ 505 | \$ 8 | \$ 1,010 | \$ 3,234 | \$ 1,356 | \$ 9,702 | \$ 2,366 |
| Variable lease costs | 769 | 198 | 8 | 409 | 1,127 | 428 | 2,775 | 885 |
| Total | \$ 4,003 | \$ 703 | \$ 6 | \$ 1,419 | \$ 4,361 | \$ 1,784 | \$ 12,477 | \$ 3,251 |

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

| (in thousands) | Six months ended June 30, | | Nine months ended September 30, | |
|--|---------------------------|----------|---------------------------------|----------|
| | 2023 | 2022 | 2023 | 2022 |
| Cash paid for amounts included in the measurements of lease liabilities: | | | | |
| Operating cash flows related to operating leases | \$ 7,416 | \$ 1,058 | \$ 9,983 | \$ 2,898 |

As of June 30, 2023 September 30, 2023, 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 9.59.3 years.

Future minimum commitments under non-cancellable non-cancelable leases as of June 30, 2023 September 30, 2023 were as follows:

| Years ending December 31, | Amount |
|--|----------------|
| | (in thousands) |
| Remainder of 2023 | \$ 2,567 |
| 2024 | 10,563 |
| 2025 | 10,868 |
| 2026 | 11,183 |
| 2027 | 11,506 |
| Thereafter | 62,735 |
| Total lease payments | \$ 109,422 |
| Less: interest | (32,615) |
| Present value of operating lease liabilities | \$ 76,807 |

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| Years ending December 31, | Amount |
|--|----------------|
| | (in thousands) |
| Remainder of 2023 | \$ 5,134 |
| 2024 | 10,563 |
| 2025 | 10,868 |
| 2026 | 11,183 |
| 2027 | 11,506 |
| Thereafter | 62,735 |
| Total lease payments | \$ 111,989 |
| Less: interest | (34,124) |
| Present value of operating lease liabilities | \$ 77,865 |

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, 2022, included in the Company's Annual Report on Form 10-K filed with the SEC on March 2, 2023. 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 2022, the first milestone was triggered and amounts due to Harvard and Broad totaled \$0.3 million. These amounts remain payable as of **June 30, 2023** **September 30, 2023**.

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 "Amended Beam Agreement").

The Company concluded the receipt of any milestone or royalty payments under the Amended Beam Agreement was not probable as of **June 30, 2023** **September 30, 2023**.

On October 27, 2023, Beam and Eli Lilly and Company entered into a transfer and delegation agreement (the "TDA"), pursuant to which Lilly acquired certain assets and other rights from Beam under the Amended Beam Agreement, including Beam's opt-in rights to co-develop and co-commercialize the Company's base editing programs for cardiovascular disease, which consist of programs targeting *PCSK9*, *ANGPTL3* and an undisclosed liver-mediated, cardiovascular target, which is further described in Note 15, "Subsequent events." The terms of the TDA have no impact on the Company's financial statements or accounting analysis of the Amended Beam Agreement.

Beam materials exchange letter agreement

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

For the three and **six** **nine** months ended **June 30, 2023** **September 30, 2023** and 2022, the Company did not purchase any materials from Beam or sell any materials to Beam.

Novartis license agreement

In October 2021, the Company entered into a license agreement with Novartis Pharma AG to obtain a non-exclusive license to lipid technology the Company is using in connection with the research and development of certain product candidates, including VERVE-102 and VERVE-201. The license agreement requires the Company to pay up to an aggregate of \$10.0 million in clinical and regulatory milestones and \$35.0 million in sales-based milestones for products that incorporate the licensed lipid technology. The milestones have not been achieved and no expense has been recorded for these milestones as of **June 30, 2023** **September 30, 2023**.

9. Collaboration and license agreements

Vertex Agreement

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Summary of 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. Additionally, in connection with the execution of the Vertex Agreement, the Company entered into a stock purchase

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agreement (the "Vertex Stock Purchase Agreement") with Vertex, pursuant to which the Company sold 1,519,756 shares of its common stock to Vertex at a price of \$23.03 per share, for an aggregate purchase price of \$35.0 million.

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

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

The Company received an upfront payment from Vertex of \$25.0 million and is eligible to receive (i) success payments of up to \$22.0 million for each product candidate (up to a maximum of \$66.0 million) that achieves the applicable development criteria, (ii) up to an aggregate of \$175.0 million in development milestones and (iii) up to an aggregate of \$165.0 million in commercial milestone payments. The Company is also eligible to receive tiered single-digit royalties on net sales, with the rate dependent upon the type of product and subject to specified reductions. Such royalty payments will terminate on a country-by-country and product-by-product basis upon the later to occur of (i) the expiration of the last to expire valid

claim under the patent rights covering such product in such country, (ii) the period of regulatory exclusivity associated with such product in such country or (iii) ten years after the first commercial sale of such product in such country.

Prior to the first patient dosing in the first Phase 1 clinical trial for the first product candidate developed under the Vertex Agreement, the Company also has the right to opt-in to a profit share arrangement pursuant to which Vertex and the Company would share the costs and net profits for all product candidates emerging from the collaboration. If the Company exercises its opt-in right, in lieu of milestones and royalties, it will be obligated to pay for a specified percentage of the development and commercialization costs, and it will have the right to receive a specified percentage of the profits from any sales of any product candidates advanced under the collaboration. At the time the Company exercises the option, it may elect a profit/cost share of up to 40% (with Vertex retaining a minimum of 60%). In order to exercise its opt-in right, the Company is required to pay a fee ranging from \$25.0 million to \$70.0 million, depending on the profit/cost percentage elected by the Company and the Company's licensed technology included in the most advanced product candidate at the time it exercises its opt-in right. Under all profit share scenarios, Vertex will control the worldwide development and commercialization of any product candidates resulting from the collaboration.

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

Accounting Analysis

The Company assessed the promised goods and services under the Vertex Agreement, in accordance with ASC Topic 606, "Revenue from Contracts with Customers" ("ASC 606"). At inception, the Vertex Agreement included the following performance obligations: (i) the research services obligation which relates to the research and development services to be provided under the Vertex Research Plan through June 30, 2023 (the "Initial Vertex Research Services") and (ii) three licensed agent material rights related to the options to obtain licenses to exploit a licensed agent, at a discount.

The Company identified \$20.0 million of fixed transaction price consisting of the \$25.0 million upfront fee offset by a discount of \$5.0 million related to the 1,519,756 shares sold to Vertex under the Vertex Stock Purchase Agreement when

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measured at fair value on the date of issuance. The Company is also entitled to reimbursement of costs incurred associated with the delivery of the Initial Vertex Research Services under the Research Plan. Services. The Company utilized the most likely amount approach and estimated the expected cost reimbursement to be \$5.8 million at inception. The Company concluded that these amounts do not require a constraint and are included in the transaction price at inception. The Company considers this estimate at each reporting date and updates the estimate based on information available. Additional consideration to

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be paid to the Company upon reaching certain milestones are excluded from the transaction price as that consideration may only be earned subsequent to an option exercise.

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

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

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

As of June 30, 2023, the The reimbursement related to the Initial Vertex Research Services is was \$5.4 million, based on the services rendered upon completion of the Initial Vertex Research Services. Services as of June 30, 2023. Upon completion of the Initial Vertex Research Services, the parties agreed upon and estimated additional services to be rendered through December 31, 2024. The Company utilized the most likely amount approach and estimated the expected cost reimbursement to be \$16.9 million which will be is being recognized on a proportional performance basis over the period of service using an input-based measurement.

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 period. As of June 30, 2023, the Company has recorded \$20.0 million as non-current deferred revenue related to the unexercised material rights. During the three and nine months ended September 30, 2022, the Company recognized \$

0.9 million of revenue associated with the Vertex Agreement related to research services performed during the period. 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, 2023, operations.

10. Common stock

In July 2022, in connection with the execution of the Vertex Agreement, the Company and Vertex also entered into the Vertex Stock Purchase Agreement, pursuant to which the Company sold 1,519,756 shares of common stock to Vertex at a price of \$23.03 per share, for an aggregate purchase price of \$35.0 million.

In July 2022, the Company completed a follow-on public offering of common stock, pursuant to which the Company issued and sold 9,583,334 shares of its common stock, including 1,250,000 shares of its common stock sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of \$27.00 per share.

The Company received net proceeds of approximately \$242.9 million after deducting underwriting discounts and offering expenses of approximately \$15.9 million. Lilly Agreement

In July 2022, the Company entered into an Open Market Sales Summary of 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, 2023, the Company did not make sales under the Sales Agreement. During the six months ended June 30, 2023, the Company sold 103,184 shares of common stock under the Sales Agreement for aggregate net proceeds of \$2.0 million, after deducting commissions and offering expenses payable by the Company. As of June 30, 2023, the Company sold 1,383,352 shares of common stock under the Sales Agreement for aggregate net proceeds of \$44.9 million, after deducting commissions and offering expenses payable by the Company.

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, 2023, 3,086,541 shares of the Company's common stock were added to the amount reserved for issuance under the 2021 Plan. As of June 30, 2023, the Company had reserved 10,144,170 shares of the Company's common stock for issuance of stock options, restricted stock, and restricted stock units, of which 3,481,809 shares remained available for future grant under the 2021 Plan. Upon effectiveness of the 2021 Plan, the Company ceased granting additional awards under the 2018 Plan.

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

| (in thousands) | Three months ended June 30, | | Six months ended June 30, | |
|--|--------------------------------|----------|------------------------------|----------|
| | 2023 | 2022 | 2023 | 2022 |
| Research and development | \$ 4,848 | \$ 2,955 | \$ 9,337 | \$ 5,421 |
| General and administrative | 4,165 | 2,694 | 7,700 | 4,432 |
| Total stock-based compensation expense | \$ 9,013 | \$ 5,649 | \$ 17,037 | \$ 9,853 |

Stock options

The following table provides a summary of stock option activity during the six months ended June 30, 2023:

| | 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, 2022 | 7,612,826 | \$ 16.10 | | |
| Granted | 2,624,742 | 21.18 | | |
| Exercised | (127,608) | 5.20 | | |
| Forfeited | (297,111) | 23.94 | | |
| Outstanding at June 30, 2023 | 9,812,849 | \$ 17.36 | 8.2 | \$ 58,881 |
| Exercisable at June 30, 2023 | 3,794,250 | \$ 11.31 | 7.3 | \$ 40,217 |
| Expected to vest after June 30, 2023 ⁽¹⁾ | 6,018,599 | \$ 21.18 | 8.8 | \$ 18,664 |

(1) This represents the number of unvested options outstanding as of June 30, 2023 that are expected to vest in the future.

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(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, 2023.

As of June 30, 2023, there was \$84.7 million of unrecognized stock-based compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.7 years.

Restricted stock units

During the six months ended June 30, 2023, the Company granted 370,500 restricted stock units under the 2021 Plan. These restricted stock units vest annually over a four-year period.

A summary of the status of and change in unvested restricted stock units as of June 30, 2023 was as follows:

| | Shares | Weighted-average grant date fair value per share |
|---|----------|--|
| Unvested restricted stock units as of December 31, 2022 | 677,825 | \$ 23.10 |
| Restricted stock units granted | 370,500 | \$ 19.43 |
| Restricted stock units vested | (50,537) | \$ 29.78 |
| Restricted stock units forfeited | (67,592) | \$ 19.59 |
| Unvested restricted stock units as of June 30, 2023 | 930,196 | \$ 21.53 |

As of June 30, 2023, there was \$17.3 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, or 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, 2023, 617,308 shares of common stock were added to the amount reserved for sale under the ESPP. As of June 30, 2023, 1,349,500 shares remained available for issuance under the ESPP. The most recent offering period ended on May 31, 2023, for which the Company issued 52,134 shares of its common stock. The current offering period commenced on June 1, 2023 and will end on November 30, 2023.

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, | |
|--|----------------|-----------|
| | 2023 | 2022 |
| Unvested restricted stock units | 930,196 | 552,375 |
| Outstanding options to purchase common stock | 9,812,849 | 7,885,217 |
| Total | 10,743,045 | 8,437,592 |

13. Income taxes

The Company's effective income tax rate was de minimis for the three and six months ended June 30, 2023 and 0.0% for the three and six months ended June 30, 2022, respectively. The income tax provision was \$0.2 million for both the three and six months ended June 30, 2023. There was no income tax provision recorded for the three and six months ended June 30, 2022. The increase in the provision for income taxes primarily relates to an increase in state income taxes based on gross interest income.

The effective income tax rate for the three and six months ended June 30, 2023 and 2022 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

An executive officer of Beam was a board member of the Company until August 2022.

In December 2021, 2023, the Company entered into a sublease agreement with Beam for laboratory and office space in Cambridge, Massachusetts, which sublease terminated in December 2022. Total rent payments under this sublease were \$0.5 million and \$1.0 million for the three and six months ended June 30, 2022, respectively.

An executive of Broad was a board member of the Company until May 2021. 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. Additional consideration under the Harvard/Broad License Agreement included antidilution rights and includes success payments. See Note 8, "License agreements," to the audited consolidated financial statements for the year ended December 31, 2022 included in the Company's Annual Report on Form 10-K filed with the SEC on March 2, 2023.

15. Subsequent events

Research and Collaboration Agreement

On June 14, 2023, the Company entered into the (the "Lilly Agreement") with Lilly Agreement for an exclusive, five-year worldwide research collaboration initially focused on advancing the Company's discovery-stage *in vivo* gene editing lipoprotein(a) program. On July 26, 2023, following expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, the Lilly Agreement became effective. Additionally, on June 14, 2023, in June 2023, in connection with the execution of the Lilly Agreement, the Company entered into the a stock purchase agreement with Lilly (the "Lilly Stock Purchase Agreement with Lilly, Agreement"), pursuant to which the Company agreed to sell and issue sold 1,552,795 shares of its the Company's common stock to Lilly, Lilly at a price of \$19.32 per share for an aggregate purchase price of \$On July 26, 2023, following HSR Clearance, the Lilly Agreement became effective. 30.0 million (the "Private Placement"). The Private Placement closed on July 31, 2023.

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Pursuant to the Lilly Agreement, the Company will be responsible for all research activities and Phase 1 clinical development of the initial target of interest—*LPA*. The Company's research and development activities will be focused on (i) identifying and engineering specific gene editing systems and *in vivo* delivery technologies directed to the relevant target; (ii) evaluating and optimizing development candidates to achieve criteria specified in the Lilly Agreement; and (iii) Phase 1 clinical development. development ("Lilly Research Services"). Lilly will reimburse the Company's research expenses and Phase 1 clinical development expenses consistent with an agreed-upon budget. budget ("Lilly Research and Development Plan"). The research term for the initial target is five years and may be extended by Lilly for up to one additional year. year ("Lilly Research Term"). The Lilly Research and Development Plan is overseen by a Joint Steering Committee ("Lilly JSC") as detailed in the Lilly Agreement. Any material amendments to the Lilly Research and Development Plan are required to be mutually agreed to by the Lilly JSC. A licensed product under the Lilly Agreement is an *in vivo* gene editing product that includes a candidate developed from the Lilly Research and Development Plan. A candidate is agreed upon when reviewed by the Lilly JSC against the candidate success criteria described in the Lilly Agreement. Upon approval of a candidate, Lilly will receive a license to exploit the licensed product, and the licensed product will continue to be developed under the Lilly Research and Development Plan through completion of the Phase 1 clinical trial for the applicable licensed product. Following completion of Phase 1 clinical trials with respect to any licensed product candidate under the Lilly Agreement, Lilly will be solely responsible for subsequent development, manufacturing and commercialization of each such product candidate resulting from the Company's research efforts.

The Under the Lilly Agreement, the Company received an upfront payment from Lilly of \$30.0 million in August 2023. The Company is also eligible to receive (i) up to an aggregate of \$465.0 190.0 million in research and development milestone payments and (ii) up to an aggregate of \$275.0 million in commercial milestone payments and payments. The Company is also eligible to receive tiered and incremental high single and low-double digit royalties on global net sales, subject to specified reductions. Such royalty payments will terminate on a country-by-country and product-by-product basis upon the latest to occur of (i) the expiration of the last-to-expire valid claim under the patent rights covering such product in such country, (ii) expiration of the period of regulatory and market exclusivity associated with such product in such country or (iii) 10 years after the first commercial sale of such product in such country.

Following completion of Phase 1 clinical development, the Company has the right to opt-in to a cost and margin share arrangement pursuant to which Lilly and the Company would share the costs and net margins for all product candidates emerging from the collaboration. If the Company exercises its opt-in right, the Company will be obligated to pay an opt-in fee in addition to funding 40%40% of the development and commercialization costs, and it will have the right to receive, in lieu of the milestones and royalties described above, 40%40% of the gross margin less eligible expenses from any sales of any product candidates advanced under the collaboration, with Lilly retaining 60%60% of the cost and margin share. Notwithstanding this opt-in right, Lilly will control the worldwide development and commercialization of any product candidates resulting from the collaboration.

Beyond the initial target of interest, upon the achievement of certain criteria and payment of additional upfront consideration, Lilly has the right to elect one additional, pre-determined target to the collaboration. The research, clinical development and commercialization of such additional target would be subject to the same terms under the Lilly Agreement as the initial target, including the Company's right to receive up to an additional \$465.0 million in research, development and commercial milestone payments, the Company's right to receive tiered and incremental high single and low-double digit royalties on global net sales and the Company's right to opt-in to a cost and margin share arrangement.

During the Lilly Research Term, Lilly can make the determination subject to the terms of the Lilly Agreement, to replace the initial target or additional target with a different specified option target. Such replacement target will be the subject of a new licensed program under the research and development program. All rights granted with respect to the replaced target will cease upon Lilly's election to select a different specified option target.

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

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for convenience upon 180 days' notice or in part, on a research plan, licensed target or product basis, for convenience upon 90 days' notice. The Company may terminate the Lilly Agreement, in part with respect to its licensed patents, if Lilly directly or indirectly challenges the enforceability, validity or scope of such patent rights, or on a licensed product-by-licensed product basis, if such licensed product ceases to be developed for a period of time.

Concurrently with the Lilly Agreement, the Company and Lilly entered into a Sublicense Option Agreement, pursuant to which the Company granted Lilly an option to obtain a non-exclusive sublicense under patent rights licensed to the Company under the Harvard/Broad License Agreement ("Lilly Option"). In consideration for the Lilly Option, Lilly paid the Company an upfront fee of \$0.3 million. For accounting purposes, the upfront payments for the Lilly Agreement and the Sublicense Option Agreement will be combined. If Lilly exercises the Lilly Option, Lilly will be required to pay a sublicense

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fee to the Company and Lilly will reimburse the Company for royalties and milestones incurred related to the sublicensed product under the Harvard/Broad License Agreement.

Accounting Analysis

The Company assessed the promised goods and services under the Lilly Agreement, in accordance with ASC 606. At inception, the Lilly Agreement included the following performance obligations: (i) the Lilly Research Services obligation which relates to the research and development services to be provided under the Lilly Research and Development Plan and (ii) two licensed product material rights related to the right to obtain licenses to exploit a licensed product associated with the initial target upon achievement of certain development criteria.

The Company identified \$28.5 million of fixed transaction price consisting of (i) the \$30.0 million upfront fee in the Lilly Agreement, (ii) the \$0.3 million upfront fee in the Lilly Option, which is combined for accounting purposes, (iii) offset by a discount of \$1.7 million related to the 1,552,795 shares sold to Lilly under the Lilly Stock Purchase Agreement when measured at fair value on the date of issuance. The Company is also entitled to reimbursement of costs incurred associated with the delivery of the Lilly Research Services. The Company utilized the most likely amount approach and estimated the expected cost reimbursement to be \$16.4 million at inception, which represents the budget for the first year of the Lilly Research Services. The remainder of the Lilly Research and Development Plan budget is subject to annual review by Lilly and the Company. The Company concluded that these amounts do not require a constraint and are included in the transaction price at inception. The Company considers this estimate at each reporting date and updates the estimate based on information available. Additional consideration to be paid to the Company upon reaching certain milestones are excluded from the transaction price at contract inception as they are not probable at this time. The probability will be re-evaluated each reporting period, and the transaction price will be updated accordingly.

On June 14, 2023

The Company has concluded that the variable consideration related to the cost reimbursement of the Lilly Research Services obligation will be allocated entirely to that obligation as the cost reimbursement relates specifically to the services being performed under the Research and Development Plan. The reimbursement of the Research and Development Services is considered to be at a market rate and therefore depicts the estimated amount it would expect to receive for this obligation. As a result, the Company allocated the fixed consideration of \$28.5 million to the two licensed product material rights based on their relative standalone selling prices. The estimated standalone selling price for each material right was based on an adjusted market assessment approach. The Company concluded that the market would be willing to pay an equal amount for each license on a standalone basis before being adjusted for the probability of the option becoming exercisable upon the successful completion of research and development activities to identify the licensed products. The Company reached this conclusion after considering (i) the downstream economics including success fees, milestones and royalties related to each licensed product being identical and (ii) both licensed products are targeting the same gene. As such, based on the relative standalone selling price for each of the material rights, the allocation of the transaction price to the separate performance obligations, at inception, is as follows:

| Performance obligation | Amount |
|--|----------------|
| | (in thousands) |
| Research services obligation | \$ 16,398 |
| First licensed product material right | 14,270 |
| Second licensed product material right | 14,270 |

| | | |
|-------|----|--------|
| Total | \$ | 44,938 |
|-------|----|--------|

The amount allocated to the Lilly Research Services obligation will be recognized on a proportional performance basis over the period of service using input-based measurements of total cost of research incurred to estimate the proportion performed and remeasured at the end of each reporting period. The amount allocated to the licensed product material rights was recorded as deferred revenue and will commence recognition upon the achievement of the candidate selection criteria or, if never achieved, it will be recognized in full upon expiry of the Lilly Research Term.

During three and nine months ended September 30, 2023, the Company recognized \$0.7 million of revenue associated with the Lilly Agreement related to the Lilly Research Services performed during the period. As of September 30, 2023, the Company has recorded \$28.5 million as non-current deferred revenue related to the unexercised material rights.

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 nine months ended September 30, 2023.

10. Common stock

In July 2022, in connection with the execution of the Vertex Agreement, the Company and Vertex also entered into the Vertex Stock Purchase Agreement, pursuant to which the Company sold 1,519,756 shares of common stock to Vertex at a price of \$23.03 per share, for an aggregate purchase price of \$35.0 million.

In July 2022, the Company completed a follow-on public offering of common stock, pursuant to which the Company issued and sold 9,583,334 shares of its common stock, including 1,250,000 shares of its common stock sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of \$27.00 per share. The Company received net proceeds of approximately \$242.9 million after deducting underwriting discounts and offering expenses of approximately \$15.9 million.

In July 2022, the Company entered into an Open Market Sales 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 September 30, 2023, the Company did not make sales under the Sales Agreement. During the nine months ended September 30, 2023, the Company sold 103,184 shares of common stock under the Sales Agreement for aggregate net proceeds of \$2.0 million, after deducting commissions and offering expenses payable by the Company. As of September 30, 2023, the Company sold 1,383,352 shares of common stock under the Sales Agreement for aggregate net proceeds of \$44.9 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 the Lilly Stock Purchase Agreement, for pursuant to which the sale and issuance of Company sold 1,552,795 shares of the

Company's common stock to Lilly at a price of \$19.32 per share, which was equal to a 15% premium to the volume-weighted average share price of common stock over the 30 trading days prior to June 14, 2023, for an aggregate purchase price of \$30.0 million. The Private Placement closed on July 31, 2023.

11. Stock-based compensation

The Lilly Stock Purchase Agreement contains customary representations, warranties 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 covenants restricted stock units to the Company's employees, officers, directors, advisors, and outside consultants for the issuance or purchase of each party. shares of the Company's common stock. The Lilly Stock Purchase Agreement also includes lock-up restrictions with respect to the maximum number of shares of common stock issued to Lilly. Pursuant 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 terms 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, 2023, 3,086,541 shares of the Lilly Stock Purchase Agreement, Lilly has agreed not Company's common stock were added to and to cause its affiliates not to, sell or transfer any the amount reserved for issuance under the 2021 Plan. As of September 30, 2023, the Company had reserved 10,144,170 shares of the shares Company's common stock for a period of time following the date of issuance of stock options, restricted stock, and restricted stock units, of which 3,278,933 shares remained available for future grant under the shares, subject to specified conditions 2021 Plan. Upon effectiveness of the 2021 Plan, the Company ceased granting additional awards under the 2018 Plan.

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

| (in thousands) | Three months ended | | Nine months ended | |
|--|--------------------|----------|-------------------|-----------|
| | September 30, | | September 30, | |
| | 2023 | 2022 | 2023 | 2022 |
| Research and development | \$ 4,895 | \$ 3,216 | \$ 14,232 | \$ 8,637 |
| General and administrative | 3,930 | 2,704 | 11,630 | 7,136 |
| Total stock-based compensation expense | \$ 8,825 | \$ 5,920 | \$ 25,862 | \$ 15,773 |

Stock options

The following table provides a summary of stock option activity during the nine months ended September 30, 2023:

| | 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, 2022 | 7,612,826 | \$ 16.10 | | |
| Granted | 2,959,242 | 20.35 | | |
| Exercised | (171,037) | 5.12 | | |
| Forfeited | (458,818) | 26.98 | | |
| Outstanding at September 30, 2023 | 9,942,213 | \$ 17.05 | 8.1 | \$ 34,298 |
| Exercisable at September 30, 2023 | 4,206,762 | \$ 11.91 | 7.1 | \$ 26,495 |
| Expected to vest after September 30, 2023 ⁽¹⁾ | 5,735,451 | \$ 20.83 | 8.7 | \$ 7,803 |

(1) This represents the number of unvested options outstanding as of September 30, 2023 that are expected to vest in the future.

(2) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that were in the money as of September 30, 2023.

As of September 30, 2023, there was \$76.8 million of unrecognized stock-based compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.6 years.

Restricted stock units

During the nine months ended September 30, 2023, the Company granted 436,340 restricted stock units under the 2021 Plan. These restricted stock units vest annually over a four-year period.

A summary of the status of and change in unvested restricted stock units as of September 30, 2023 was as follows:

| | Shares | Weighted- average grant date fair value per share |
|--|-----------|--|
| Unvested restricted stock units as of December 31, 2022 | 677,825 | \$ 23.10 |
| Restricted stock units granted | 436,340 | \$ 19.53 |
| Restricted stock units vested | (127,123) | \$ 20.95 |
| Restricted stock units forfeited | (103,349) | \$ 24.05 |
| Unvested restricted stock units as of September 30, 2023 | 883,693 | \$ 21.54 |

As of September 30, 2023, there was \$16.3 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 3.1 years.

2021 Amended and Restated Employee Stock Purchase Plan

In June 2021, the board of directors adopted, and the Company's stockholders approved, the 2021 Employee Stock Purchase Plan, or the ESPP, as amended and restated, which became effective on June 16, 2021. The shares reserved for issuance pursuant to the ESPP are subject to an annual increase through January 1, 2031. On January 1, 2023, 617,308 shares of common stock were added to the amount reserved for sale under the ESPP. As of September 30, 2023, 1,349,500 shares remained available for issuance under the ESPP. The most recent offering period ended on May 31, 2023, for which the Company issued 52,134 shares of its common stock. The current offering period commenced on June 1, 2023 and will end on November 30, 2023.

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

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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 September 30, | |
|--|---------------------|-----------|
| | 2023 | 2022 |
| Unvested restricted stock units | 883,693 | 609,400 |
| Outstanding options to purchase common stock | 9,942,213 | 7,555,094 |
| Total | 10,825,906 | 8,164,494 |

13. Income taxes

The Company's effective income tax rate was de minimis for the three and nine months ended September 30, 2023 and 0.0% for the three and nine months ended September 30, 2022, respectively. The income tax provision was \$0.1 million and \$0.2 million for both the three and nine months ended September 30, 2023, respectively. There was no income tax provision recorded for the three and nine months ended September 30, 2022. The increase in the provision for income taxes primarily relates to an increase in state income taxes based on gross interest income.

The effective income tax rate for the three and nine months ended September 30, 2023 and 2022 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

An executive officer of Beam was a board member of the Company until August 2022.

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

An executive of Broad was a board member of the Company until May 2021. In March 2019, the Company 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. Additional consideration under the Harvard/Broad License Agreement included antidilution rights and includes success payments. See Note 8, "License agreements," to the audited consolidated financial statements for the year ended December 31, 2022 included in the Company's Annual Report on Form 10-K filed with the SEC on March 2, 2023.

15. Subsequent events

Transfer of product rights under Beam license agreement

On October 27, 2023, pursuant to the TDA between Lilly and Beam, Lilly acquired certain rights previously held by Beam under the Amended Beam Agreement, including the right to opt-in to the Company's PCSK9 and ANGPTL3 programs to share 33% of worldwide development expenses and to jointly commercialize and share profits and expenses related to commercialization in the United States on a 50/50 basis. The Company holds all product rights for the PCSK9 and ANGPTL3 programs outside the United States. Additionally, for a third undisclosed cardiovascular disease target, Lilly acquired Beam's right to opt-in to share 35% of worldwide expenses of the development of such licensed product, as well as jointly commercialize and share 35% of the profits and expenses of commercializing such licensed product worldwide. Under the Amended Beam Agreement, the Company retains control of the development and commercialization of all collaboration products. Lilly also acquired Beam's right to receive the same future milestone or royalty payments that were payable to Beam under the Amended Beam Agreement with respect to certain development or commercial activities outside the United States or in the event Lilly does not exercise a program opt-in right.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 2, 2023. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed in "Risk Factors" in Part II, Item 1A. You should carefully read the section entitled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

Overview

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

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

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

Through June 30, 2023 As of September 30, 2023, we had raised an aggregate of \$863.7 million \$893.6 million in gross proceeds from sales of our preferred and common stock in private placements and common stock in public offerings.

In June 2023, we entered into a Research and Collaboration Agreement, or the Lilly Agreement, with Lilly for an exclusive, five-year worldwide research collaboration initially focused on advancing our discovery-stage *in vivo* gene editing Lp(a) program. The Lilly Agreement became effective in July 2023 upon the expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or HSR Clearance, amended. Pursuant to the Lilly Agreement, we received the upfront payment of \$30.0 million in August 2023. We are eligible to receive up to an aggregate

of \$465.0 million in research, development and commercial milestone payments and tiered and incremental high single and low-double digit royalties on global net sales, subject to specified reductions.

In June 2023, in connection with the execution of the Lilly Agreement, we also entered into a stock purchase agreement with Lilly, for the sale and issuance of 1,552,795 shares of our common stock to Lilly at a price of \$19.32 per share, which

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was equal to a 15% premium to the volume-weighted average share price of our common stock over the 30 trading days prior to June 14, 2023, for an aggregate purchase price of \$30.0 million, or the Lilly Private Placement. The Lilly Private Placement closed on July 31, 2023.

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 nine months ended June 30, 2023 September 30, 2023 were \$54.0 million \$45.8 million and \$106.0 million \$151.7 million, respectively. As of June 30, 2023 September 30, 2023, we had an accumulated deficit of \$450.2 million \$496.0 million.

We expect to continue to incur significant expenses and increasing operating losses in connection with ongoing development activities related to our portfolio of programs as we advance VERVE-101 in our ongoing heart-1 clinical trial; continue our preclinical development of other product candidates, including VERVE-102, our product candidate targeting PCSK9 using our GalNAc-LNP delivery technology, and VERVE-201, our product candidate targeting ANGPTL3; advance these product candidates toward clinical development; further develop base editing and novel gene editing technology, delivery technology and manufacturing capabilities; seek to discover and develop additional product candidates; 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, 2023 September 30, 2023, we had cash, cash equivalents and marketable securities of \$462.5 million \$485.2 million. We believe that our existing cash, cash equivalents and marketable securities including the \$30.0 million received from Lilly in the Private Placement and the \$30.0 million upfront payment received from Lilly pursuant to the Lilly Agreement in August 2023, will enable us to fund our operating expenses and capital expenditure requirements into 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

VERVE-101

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

We are advancing VERVE-101 for the treatment of patients with heterozygous familial hypercholesterolemia, or HeFH, the estimated prevalence of which is roughly one in 250, which translates to approximately 1.3 million people in the United States. We are strategically developing VERVE-101 initially in patients with HeFH, recognizing that the unmet need is highest in those patients and the benefit-risk profile may be more favorable. We plan to expand clinical development of VERVE-101 in a stepwise fashion beyond HeFH for the treatment of patients with established ASCVD who are not at LDL-C goal on oral therapy. Ultimately, we believe that VERVE-101 may be useful to people at risk for ASCVD as a preventative measure in the general population.

Ongoing heart-1 clinical trial

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Our heart-1 clinical trial, a global Phase 1b open-label clinical trial, is designed to enroll approximately 40 adult patients with HeFH who have established ASCVD and evaluate the safety and tolerability of VERVE-101 administration, with additional analyses for pharmacokinetics and reductions changes in blood PCSK9 protein and LDL-C. LDL-C levels. The trial includes three

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parts – (A) a single ascending dose portion, followed by (B) an expansion single-dose cohort, in which additional participants will receive the selected potentially therapeutic dose and (C) an optional second-dose cohort, in which eligible participants in lower dose cohorts in Part A have the option to receive a second treatment at the selected potentially

therapeutic dose. During our interactions with regulators in New Zealand and the United Kingdom as well as the U.S. Food and Drug Administration, or FDA, country-specific protocols have been developed to account for various modifications to eligibility, design, and conduct in each country.

We have received clearance of our clinical trial applications, or CTAs, for VERVE-101 in New Zealand and the United Kingdom in 2022, and in July 2022, we announced that the first patient had been dosed with VERVE-101 in our heart-1 clinical trial. Enrollment efforts are Our ongoing heart-1 clinical trial is currently being conducted at sites in New Zealand and the United Kingdom.

In October 2023, the FDA lifted the clinical hold and cleared our investigational new drug, or IND, application to conduct a clinical trial in the United States evaluating VERVE-101 for the treatment of patients with HeFH. With the clearance of the IND, we plan to begin the process of activating clinical trial sites in the United States for the heart-1 clinical trial.

We expect to report the initial safety, tolerability and pharmacodynamic data, as well as blood PCSK9 protein and blood LDL-C data levels for the four cohorts in the dose-escalation portion of the heart-1 clinical trial in at the fourth quarter of 2023.

Our investigational new drug, or IND, application to the U.S. Food and Drug Administration, or FDA, to conduct a clinical trial in the United States evaluating VERVE-101 in patients with HeFH is currently American Heart Association's Scientific Sessions 2023 on hold. We are continuing to work with the FDA to resolve the hold on the IND for VERVE-101. Based on the progress of the heart-1 clinical trial, we expect enrollment to be completed outside the United States. November 12, 2023.

VERVE-102

VERVE-102, our second product candidate targeting *PCSK9* delivered using our GalNAc-LNP delivery technology, is also designed to permanently turn off the *PCSK9* gene in the liver and is also being developed initially for the treatment of HeFH. VERVE-101 and VERVE-102 share an identical guide RNA targeting *PCSK9* as well as similar mRNA expressing an adenine base editor and differ principally in the LNP delivery system. We believe that delivering our *PCSK9*-targeting edits via our GalNAc-LNP, which binds to the asialoglycoprotein receptor, or ASGPR, in addition to LDLR, may provide another opportunity to address this target. Preclinical development to support a regulatory submission for VERVE-102 began in early 2022, and we expect to initiate a Phase 1b clinical trial with VERVE-102 for patients with HeFH in the first half of 2024, subject to regulatory approval.

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 homozygous familial hypercholesterolemia, or HoFH, the estimated prevalence of which is roughly one in 250,000 which translates to approximately 1,300 patients in the United States, as well as for refractory hypercholesterolemia defined as people with ASCVD who are not at LDL-C goal on oral therapy and a PCSK9 inhibitor. Ultimately, we believe that VERVE-201 may also be useful to people at risk for ASCVD as a preventative measure in the general population. 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 are conducting preclinical studies and expect to initiate a Phase 1b clinical trial with VERVE-201 in the second half of 2024, subject to regulatory approval.

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" and Note 15, "Subsequent events" to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

On October 27, 2023, pursuant to a transfer and delegation agreement, or the TDA, between Lilly and Beam Therapeutics Inc., or Beam, Lilly acquired certain rights previously held by Beam under our amended and restated collaboration and license agreement with Beam, or the ARCLA, including the right to opt-in to our PCSK9 and ANGPTL3 programs to share 33% of worldwide development expenses and to jointly commercialize and share profits and expenses related to commercialization in the United States on a 50/50 basis. We hold all product rights for the PCSK9 and ANGPTL3 programs outside the United States. Additionally, for a third undisclosed cardiovascular disease target, Lilly acquired Beam's right to opt-in to share 35% of worldwide expenses of the development of such licensed product, as well as jointly commercialize and share 35% of the profits and expenses of commercializing such licensed product worldwide. Under the ARCLA, we retain control of the development and commercialization of all collaboration products. Lilly also acquired Beam's right to receive the same future milestone or royalty payments that were payable to Beam under the ARCLA with

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respect to certain development or commercial activities outside the United States or in the event Lilly does not exercise a program opt-in right.

Under the terms of the TDA, Beam received a \$200 million upfront payment and a \$50 million equity investment from Lilly and is eligible to receive from Lilly up to \$350 million in potential future development-stage payments upon the completion of certain clinical, regulatory and alliance events.

Components of our results of operations

Revenue

During the three and six months ended June 30, 2023 and September 30, 2023, we recognized \$2.1 million, \$3.1 million and \$3.5 million, \$6.6 million, respectively, in collaboration revenue under the Vertex Agreement and Lilly Agreement. We expect revenue related to this collaboration, these collaborations to increase as efforts under the collaboration continue, and we expect to record additional revenues related to the collaboration with Lilly in the future. 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; 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, 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.

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

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- raising additional funds necessary to complete preclinical and clinical development of our product candidates;
- the timing of filing and acceptance of INDs or comparable foreign applications that allow commencement of planned and future clinical trials for our product candidates;
- the successful initiation, enrollment and completion of clinical trials;
- our ability to achieve positive results from our ongoing, 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;

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- 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, including the COVID-19 pandemic.

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

General and administrative expenses

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

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

Other income

Change in fair value of 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 high nine-digit dollar amount to \$10.0 billion, or sale of our company for consideration in excess of those thresholds. In the event of a change of control of our company or a sale of our company, we are required to pay any related success payment in cash within a specified period following such event. Otherwise, the success payments may be settled at our option in either cash or shares of our common stock, or a combination of cash

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and shares of our common stock. The remaining potential 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 (expense) while the instrument is outstanding.

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

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.

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Income tax

The provision for income taxes was \$0.1 million and \$0.2 million for both the three and six nine months ended June 30, 2023. September 30, 2023, respectively. There was no provision for income taxes for the three and six nine months ended

June 30, 2022 September 30, 2022. The increase in the provision for income taxes primarily relates to an increase in state income taxes based on gross interest income.

Results of operations

Comparison of three months ended June 30, 2023 September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended June 30, 2023 September 30, 2023 and 2022:

| (in thousands) | Three months ended June 30, | | | Three months ended September 30, | | |
|---|--------------------------------|--------|----------|-------------------------------------|---------|----------|
| | 2023 | 2022 | Change | 2023 | 2022 | Change |
| Collaboration revenue | \$ 2,093 | \$ - | \$ 2,093 | \$ 3,117 | \$ 929 | \$ 2,188 |
| Operating expenses: | | | | | | |
| Research and development | | | 14,13 | | | |
| | 47,260 | 33,125 | 5 | 43,765 | 35,197 | 8,568 |
| General and administrative | 13,416 | 9,067 | 4,349 | 11,686 | 9,592 | 2,094 |
| Total operating expenses | | | 18,48 | | | 10,66 |
| | 60,676 | 42,192 | 4 | 55,451 | 44,789 | 2 |
| Loss from operations | (58,58 | (42,19 | (16,3 | (52,33 | (43,86 | (8,47 |
| | 3) | 2) | 91) | 4) | 0) | 4) |
| Other income: | | | | | | |
| Other income (expense): | | | | | | |
| Change in fair value of success payment liability | | | (1,60 | | | |
| | (662) | 938 | 0) | 802 | (3,306) | 4,108 |
| Interest and other income, net | 5,438 | 308 | 5,130 | 5,841 | 1,976 | 3,865 |
| Total other income | 4,776 | 1,246 | 3,530 | | | |
| Total other income (expense), net | | | | 6,643 | (1,330) | 7,973 |
| Loss before provision for income taxes | (53,80 | (40,94 | (12,8 | (45,69 | (45,19 | |
| | 7) | 6) | 61) | 1) | 0) | (501) |
| Provision for income taxes | (176) | - | (176) | (67) | - | (67) |
| Net loss | (53,98 | (40,94 | (13,0 | (45,75 | (45,19 | |
| | \$ 3) | \$ 6) | \$ 37) | \$ 8) | \$ 0) | \$ (568) |

Collaboration revenue

Collaboration revenue was \$2.1 million \$3.1 million and \$0.9 million for the three months ended June 30, 2023 September 30, 2023 and 2022, respectively. During the three months ended September 30, 2023, all of which collaboration revenue included \$2.4 million related to research services performed under and cost reimbursement from the Vertex Agreement and \$0.7 million related to research services and cost reimbursement from the Lilly Agreement. We did not record any The increase in collaboration revenue for in the three months ended June 30, 2022.

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September 30, 2023 was largely a result of an increase in our research services and cost reimbursements related to the Vertex Agreement and 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, 2023 September 30, 2023 and 2022:

| (in thousands) | Three months ended June 30, | | | Three months ended September 30, | | |
|--|-----------------------------|-------|--------|----------------------------------|-------|--------|
| | 2023 | 2022 | Change | 2023 | 2022 | Change |
| Employee-related expenses | 17,2 | 10,9 | 6,29 | 17,3 | 12,3 | 4,9 |
| External expenses associated with preclinical studies performed by outside consultants, including third-party CROs | \$ 10 | \$ 17 | \$ 3 | \$ 46 | \$ 51 | \$ 95 |
| Raw material costs and external expenses associated with manufacturing activities, including third-party CMOs | 5,72 | 7,46 | (1,7 | 4,95 | 7,59 | (2,6 |
| | 3 | 2 | 39) | 4 | 5 | 41) |
| License and milestone payments | 12,1 | 5,55 | 6,64 | 8,10 | 5,84 | 2,2 |
| | 93 | 2 | 1 | 5 | 2 | 63 |
| | | 3,04 | (3,0 | | 1,08 | (1,0 |
| | 2 | 7 | 45) | 40 | 2 | 42) |
| Lab supplies | 4,76 | 2,36 | 2,39 | 3,96 | 3,08 | |
| | 8 | 9 | 9 | 7 | 3 | 884 |
| Facility-related costs (including depreciation) | 4,56 | 1,60 | 2,96 | 5,10 | 2,45 | 2,6 |
| | 5 | 2 | 3 | 1 | 1 | 50 |
| Clinical trial costs | | 1,30 | (54 | 1,91 | | 1,0 |
| | 757 | 5 | 8) | 1 | 867 | 44 |
| | 2,04 | | 1,17 | 2,34 | 1,92 | |
| Other research and development costs | 2 | 871 | 1 | 1 | 6 | 415 |

| | | | | | | |
|---|-------|-------|-------|-------|-------|-------|
| | 47,2 | 33,1 | 14,1 | 43,7 | 35,1 | 8,5 |
| Total research and development expenses | \$ 60 | \$ 25 | \$ 35 | \$ 65 | \$ 97 | \$ 68 |

Research and development expenses were \$47.3 million \$43.8 million for the three months ended June 30, 2023 September 30, 2023, compared to \$33.1 million \$35.2 million for the three months ended June 30, 2022 September 30, 2022. The increase of approximately \$14.1 million \$8.6 million was primarily due to the following:

- an increase of \$6.3 million approximately \$4.9 million in employee-related expenses, including an increase of \$1.9 million \$1.7 million in stock-based compensation, driven by an increase in headcount of employees involved in research and development activities;

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- an increase of \$6.6 million in raw material costs and external expenses associated with developing and validating our manufacturing activities, including third-party contract manufacturing organizations, or CMOs, for use in our preclinical studies and our heart-1 clinical trial;
- an increase of \$2.4 million in lab supplies due to increased activities related to our pipeline and research efforts;
- an increase of approximately \$2.9 million \$2.7 million in facility-related costs (including depreciation) and other allocated miscellaneous expenses due to increased investment in research and development as well as additional space leased at 201 Brookline Avenue;
- an increase of \$2.3 million in raw material costs and external expenses associated with manufacturing activities, including third-party CMOs, for use in our preclinical studies and our heart-1 clinical trial;
- an increase of \$1.0 million in clinical trial costs associated with our heart-1 clinical trial and related long term follow up study;
- an increase of \$0.9 million in lab supplies due to increased activities related to our pipeline and research efforts; and
- an increase of approximately \$1.1 million \$0.4 million in other research and development costs, primarily due to an increase in software subscriptions and other IT related costs.

These increases were partially offset by the following:

- a decrease of \$3.0 million in research and development expense attributed to license and milestone payments;
- a decrease of \$1.7 million \$2.6 million in external expenses associated with preclinical studies (primarily animal-study costs performed by outside consultants, including third-party CROs; and
- a decrease of \$0.5 million \$1.0 million in clinical trial costs associated with our heart-1 clinical trial. research and development expense attributed to license and milestone payments.

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

General and administrative expenses

General and administrative expenses were \$13.4 million \$11.7 million for the three months ended June 30, 2023 September 30, 2023, compared to \$9.1 million \$9.6 million for the three months ended June 30, 2022 September 30, 2022. The increase of \$4.3 million \$2.1 million was primarily attributable to the following:

- an increase of \$3.0 million \$2.3 million in personnel, employee-related expenses, including an increase of \$1.5 million \$1.2 million in stock-based compensation expense, driven by an increase in headcount to support our growth; partially offset by
- an increase a decrease of \$0.6 million \$0.2 million in professional service fees, primarily due to increased legal, audit, tax and consulting services; and
- an increase of \$0.7 million in facility and other expenses. fees.

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

Other income (expense)

Change in fair value of success payment liability

During the three months ended June 30, 2023 September 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 \$0.8 million recorded as other income. During the three months ended September 30, 2022, 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 \$3.3 million recorded as other expense. During

Interest and other income, net

The increase of \$3.9 million in interest and other income, net for the three months ended June 30, 2022 September 30, 2023 compared to the three months ended September 30, 2022 was primarily attributable to higher interest rates earned on higher marketable securities balances.

Comparison of nine months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022:

| (in thousands) | Nine months ended September 30, | | Change |
|---|------------------------------------|-----------|----------|
| | 2023 | 2022 | |
| Collaboration revenue | \$ 6,614 | \$ 929 | \$ 5,685 |
| Operating expenses: | | | |
| Research and development | 138,135 | 92,811 | 45,324 |
| General and administrative | 37,655 | 26,095 | 11,560 |
| Total operating expenses | 175,790 | 118,906 | 56,884 |
| Loss from operations | (169,176) | (117,977) | (51,199) |
| Other income: | | | |
| Change in fair value of success payment liability | 878 | (691) | 1,569 |

| | | | |
|--|--------------|--------------|-------------|
| Interest and other income, net | 16,825 | 2,366 | 14,459 |
| Total other income | 17,703 | 1,675 | 16,028 |
| Loss before provision for income taxes | (151,473) | (116,302) | (35,171) |
| Provision for income taxes | (243) | - | (243) |
| Net loss | \$ (151,716) | \$ (116,302) | \$ (35,414) |

Collaboration Revenue

Collaboration revenue was \$6.6 million and \$0.9 million for the nine months ended September 30, 2023 and 2022, respectively. During the nine months ended September 30, 2023, collaboration revenue included \$5.9 million related to research services and cost reimbursement from the Vertex Agreement and \$0.7 million related to the research services and cost reimbursement from the Lilly Agreement. The increase in collaboration revenue in the nine months ended

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September 30, 2023 was largely a result of an increase in our research services and cost reimbursements related to the Vertex Agreement and 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 nine months ended September 30, 2023 and 2022:

| (in thousands) | Nine months ended September 30, | | Change |
|--|------------------------------------|-----------|-----------|
| | 2023 | 2022 | |
| Employee-related expenses | \$ 50,799 | \$ 32,200 | \$ 18,599 |
| External expenses associated with preclinical studies performed by outside consulting services, including third-party CROs | 18,394 | 21,297 | (2,903) |
| Raw material costs and external expenses associated with manufacturing activities, including third-party CMOs | 30,851 | 15,499 | 15,352 |
| License and milestone payments | (122) | 4,483 | (4,605) |
| Lab supplies | 13,614 | 6,858 | 6,756 |
| Facility-related costs (including depreciation) | 14,120 | 5,482 | 8,638 |
| Clinical trial costs | 4,343 | 2,184 | 2,159 |
| Other research and development costs | 6,136 | 4,808 | 1,328 |
| Total research and development expenses | \$ 138,135 | \$ 92,811 | \$ 45,324 |

Research and development expenses were \$138.1 million for the nine months ended September 30, 2023, compared to \$92.8 million for the nine months ended September 30, 2022. The increase of \$45.3 million was primarily due to the following:

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- an increase of \$18.6 million in employee-related expenses, including an increase of \$5.6 million in stock-based compensation, driven by an increase in headcount of employees involved in research and development activities;
- an increase of \$15.4 million in raw material costs and external expenses associated with manufacturing activities, including third-party CMOs, for use in our preclinical studies and our heart-1 clinical trial;
- an increase of approximately \$6.7 million in lab supplies due to increased activities related to our pipeline and research efforts and increase in research based employees;
- an increase of \$8.6 million in facility-related costs (including depreciation) and other allocated miscellaneous expenses due to increased investment in research and development as well as additional space leased at 201 Brookline Avenue;
- an increase of \$2.2 million in clinical trial costs associated with our heart-1 clinical trial and related long term follow up study; and
- an increase of \$1.3 million in other research and development costs, primarily due to an increase in software subscriptions and other IT related costs.

These increases were partially offset by the following:

- a decrease of \$4.6 million in research and development expense attributed to license and milestone payments; and
- a decrease of \$2.9 million in external expenses associated with preclinical studies (primarily animal-study costs) performed by outside consultants, including third-party CROs.

General and administrative expenses

General and administrative expenses were \$37.7 million for the nine months ended September 30, 2023, compared to \$26.1 million for the nine months ended September 30, 2022. The increase of \$11.6 million was primarily attributable to the following:

- an increase of \$9.0 million in employee-related expenses, including an increase of \$4.5 million in stock-based compensation expense, driven by an increase in headcount to support our growth;
- an increase of \$0.9 million in professional service fees, primarily due to increased legal, audit, tax and consulting services; and
- an increase of \$1.7 million in facility and other expenses.

Other income (expense)

Change in fair value of success payment liability

During the nine months ended September 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 \$0.9 million recorded as other income.

Interest and other income, net

The increase of \$5.1 million in interest and other income, net for During the three nine months ended June 30, 2023 compared to the three months ended June 30, 2022 was primarily attributable to higher interest rates.

Comparison of six months ended June 30, 2023 and 2022

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The following table summarizes our results of operations for the six months ended June 30, 2023 and 2022:

| (in thousands) | Six months ended June 30, | | Change |
|---|------------------------------|-------------|-------------|
| | 2023 | 2022 | |
| Collaboration revenue | \$ 3,497 | \$ - | \$ 3,497 |
| Operating expenses: | | | |
| Research and development | 94,370 | 57,614 | 36,756 |
| General and administrative | 25,969 | 16,503 | 9,466 |
| Total operating expenses | 120,339 | 74,117 | 46,222 |
| Loss from operations | (116,842) | (74,117) | (42,725) |
| Other income: | | | |
| Change in fair value of success payment liability | 76 | 2,615 | (2,539) |
| Interest and other income, net | 10,984 | 390 | 10,594 |
| Total other income | 11,060 | 3,005 | 8,055 |
| Loss before provision for income taxes | (105,782) | (71,112) | (34,670) |
| Provision for income taxes | (176) | - | (176) |
| Net loss | \$ (105,958) | \$ (71,112) | \$ (34,846) |

Collaboration Revenue

Collaboration revenue was \$3.5 million for the six months ended June 30, 2023 September 30, 2022, all of which related to the Vertex Agreement. We did not record any revenue for the six months ended June 30, 2022.

Research and development expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2023 and 2022:

| (in thousands) | Six months ended June 30, | | Change |
|--|------------------------------|-----------|-----------|
| | 2023 | 2022 | |
| Employee-related expenses | \$ 33,453 | \$ 19,849 | \$ 13,604 |
| External expenses associated with preclinical studies performed by outside consulting services, including third-party CROs | 13,440 | 13,702 | (262) |
| Raw material costs and external expenses associated with manufacturing activities, including third-party CMOs | 22,746 | 9,657 | 13,089 |

| | | | |
|---|-----------|-----------|-----------|
| License and milestone payments | (161) | 3,400 | (3,561) |
| Lab supplies | 9,647 | 3,775 | 5,872 |
| Facility-related costs (including depreciation) | 9,019 | 3,031 | 5,988 |
| Clinical trial costs | 2,432 | 1,317 | 1,115 |
| Other research and development costs | 3,794 | 2,883 | 911 |
| Total research and development expenses | \$ 94,370 | \$ 57,614 | \$ 36,756 |

Research and development expenses were \$94.4 million for the six months ended June 30, 2023, compared to \$57.6 million for the six months ended June 30, 2022. The increase of \$36.8 million was primarily due to the following:

- an increase of \$13.6 million in employee-related expenses, including an increase of \$3.9 million in stock-based compensation, driven by an increase in headcount of employees involved in research and development activities;
- an increase of \$13.1 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 our heart-1 clinical trial;
- an increase of \$5.9 million in lab supplies due to increased activities related to our pipeline and research efforts and increase in research based employees;
- an increase of \$6.0 million in facility-related costs (including depreciation) and other allocated miscellaneous expenses due to increased investment in research and development as well as additional space leased at 201 Brookline Avenue;
- an increase of \$1.1 million in clinical trial costs associated with our heart-1 clinical trial; and
- an increase of approximately \$1.0 million in other research and development costs, primarily due to an increase in software subscriptions and other IT related costs.

These increases were partially offset by the following:

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- a decrease of \$3.6 million in research and development expense attributed to license and milestone payments; and
- a decrease of \$0.3 million in external expenses associated with preclinical studies (primarily animal-study costs) performed by outside consultants, including third-party CROs.

General and administrative expenses

General and administrative expenses were \$26.0 million for the six months ended June 30, 2023, compared to \$16.5 million for the six months ended June 30, 2022. The increase of \$9.5 million was primarily attributable to the following:

- an increase of \$6.7 million in personnel, including an increase of \$3.3 million in stock-based compensation expense, driven by an increase in headcount to support our growth;
- an increase of \$1.2 million in professional service fees, primarily due to increased legal, audit, tax and consulting services; and
- an increase of \$1.6 million in facility and other expenses.

Other income (expense)

Change in fair value of success payment liability

During the six months ended June 30, 2023 and 2022, the change in fair value of the success payments payment liability was primarily due to the decrease increase in the fair value of our common stock, which resulted in a fair value adjustment of \$0.1 million and \$2.6 million, respectively, \$0.7 million recorded to other income expense.

Interest and other income, net

The increase of \$10.6 million \$14.5 million in interest and other income, net for the six nine months ended June 30, 2023 September 30, 2023 compared to the six nine months ended June 30, 2022 September 30, 2022 was primarily attributable to higher interest rates earned on higher marketable securities balances and increased interest rates.balances.

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 collaboration collaborations and related private placements. Through June 30, 2023 September 30, 2023, we had raised an aggregate of \$863.7 million \$893.6 million in gross proceeds from sales of our preferred stock and common stock in private placements and common stock in our IPO, our follow-on public offering, and our ATM equity offering program.

As of June 30, 2023 September 30, 2023, we had \$462.5 million \$485.2 million in cash, cash equivalents and marketable securities.

In July 2023, we sold and issued 1,552,795 shares of our common stock to Lilly in connection with the Lilly Private Placement at a price of \$19.32 per share for an aggregate purchase price of \$30.0 million. Additionally, we received \$30.0 million as an upfront payment from Lilly in August 2023 pursuant to the Lilly Agreement.

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

In July 2022, we also issued and sold 9,583,334 shares of our common stock, including 1,250,000 shares of common stock sold pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock, at a public offering price of \$27.00 per share, for aggregate net proceeds of approximately \$242.9 million after deducting underwriting discounts and commissions and offering expenses of approximately \$15.9 million payable by us.

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. We agreed to pay Jefferies a commission of up to 3.0% of the aggregate gross sale proceeds of any shares sold by Jefferies under the Sales Agreement. Any sales under the Sales Agreement will be made pursuant to our registration statement on Form S-3 (File No 333-267578), which became effective on September 23, 2022, with an aggregate offering price of up to \$200.0 million. During the three months ended June 30, 2023 September 30, 2023, we did not make any sales under the Sales Agreement. During the six nine months ended June 30, 2023 September 30, 2023, we sold 103,184

shares of our common stock under the Sales Agreement for aggregate net proceeds of \$2.0 million, after deducting commissions and offering expenses payable by us. As of June 30, 2023 September 30, 2023, we have sold 1,383,352 shares of common stock under the Sales

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Agreement for aggregate net proceeds of \$44.9 million, after deducting commissions and offering expenses payable by us.

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Cash flows

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

| (in thousands) | Six months ended June 30, | | Nine months ended September 30, | |
|---|------------------------------|-------------|------------------------------------|-------------|
| | 2023 | 2022 | 2023 | 2022 |
| Net cash used in operating activities | \$ (97,058) | \$ (60,265) | \$ (108,869) | \$ (89,440) |
| Net cash provided by investing activities | 48,417 | 67,874 | 36,583 | 12,358 |
| Net cash provided by financing activities | 3,271 | 950 | 35,194 | 289,358 |
| Increase (decrease) in cash, cash equivalents and restricted cash | \$ (45,370) | \$ 8,559 | \$ (37,092) | \$ 212,276 |

Operating activities

For the six nine months ended June 30, 2023 September 30, 2023, net cash used in operating activities was \$97.1 million \$108.9 million, consisting primarily of our net loss of \$106.0 million \$151.7 million, in addition to \$7.6 million \$11.0 million associated with the non-cash accretion of discounts on our marketable securities \$0.1 million and \$0.9 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. liability. These amounts were partially offset by non-cash expenses including stock-based compensation of \$17.0 million \$25.9 million, depreciation expense of \$2.5 million \$3.9 million, and non-cash lease expense of \$3.3 million.

For the six months ended June 30, 2022 \$5.0 million, net cash used in operating activities was \$60.3 million, consisting primarily of our net loss of \$71.1 million in addition to the non-cash change in the fair value of the success payment liability of \$2.6 million. These amounts were partially offset by and net changes in our operating assets and liabilities of approximately \$0.1 million and \$19.9 million.

For the nine months ended September 30, 2022, net cash used in operating activities was \$89.4 million, consisting primarily of our net loss of \$116.3 million, partially offset by non-cash expenses including including: \$0.7 million associated with the fair value change in success payments liability, stock-based compensation of \$9.9 million \$15.8 million, depreciation

expense of \$1.2 million \$1.9 million, non-cash lease expense of \$1.0 million and \$2.3 million, amortization of investment premiums on of \$1.1 million and net changes in our marketable securities operating assets and liabilities of \$1.2 million \$5.1 million.

Investing activities

For the six nine months ended June 30, 2023 September 30, 2023, net cash provided by investing activities was \$48.4 million \$36.6 million and consisted of maturities of marketable securities of \$301.3 million \$438.5 million, partially offset by purchases of marketable securities of \$394.8 million and purchases of property and equipment of \$7.1 million, primarily related to lab equipment.

For the nine months ended September 30, 2022, net cash provided by investing activities was \$12.4 million and consisted of maturities of marketable securities of \$242.7 million, partially offset by purchases of marketable securities of approximately \$246.9 million \$222.0 million and purchases of property and equipment of \$6.0 million, primarily related to lab equipment.

For the six months ended June 30, 2022, net cash provided by investing activities was \$67.9 million and consisted of maturities of marketable securities of approximately \$147.7 million, partially offset by purchases of marketable securities of \$74.2 million and purchases of property and equipment of \$5.6 million \$8.3 million, primarily related to lab equipment.

Financing activities

For the six nine months ended June 30, 2023 September 30, 2023, net cash provided by financing activities was \$3.3 million \$35.2 million, consisting primarily of net proceeds from the Lilly Private Placement of \$31.7 million, net proceeds from the sale of our common stock under the Sales Agreement of \$1.9 million, proceeds from exercises of stock options of \$0.7 million \$0.9 million and proceeds from the issuance of shares through our employee stock purchase plan of \$0.7 million.

For the six nine months ended June 30, 2022 September 30, 2022, net cash provided by financing activities was \$1.0 million \$289.4 million, consisting primarily of net proceeds from the sale of our common stock of \$247.3 million in our July 2022 public offering, proceeds of \$40.0 million from the Vertex Private Placement, proceeds from exercises of stock options of approximately \$0.7 million \$1.8 million, and proceeds from the issuance of shares through our employee stock purchase plan of \$0.3 million.

Funding requirements

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

Specifically, our expenses will increase if and as we:

- conduct our ongoing heart-1 clinical trial for VERVE-101 in New Zealand and the United Kingdom, and if our IND application is cleared, upon activation of clinical trial sites, in the United States;
- continue our current research programs and our preclinical development of product candidates, including VERVE-102 and VERVE-201;

- seek to identify additional research programs and additional product candidates;
- advance our existing and future product candidates into clinical development;

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- 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 under 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, as such rights to receive future milestone payments were transferred by Beam to Lilly in October 2023, under our amended and restated collaboration and license agreement with Beam, or the Beam Agreement, ARCLA, milestone payments to Acuitas under our non-exclusive license agreement with Acuitas, or the Acuitas Agreement, milestone payments or success payments to Broad and Harvard under our license agreement with Broad and Harvard (as amended, the Cas9 License Agreement), and milestone payments to 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, 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.

As of June 30, 2023 September 30, 2023, we had cash, cash equivalents and marketable securities of \$462.5 million \$485.2 million. We believe that our existing cash, cash equivalents and marketable securities including the \$30.0 million received from Lilly in the Private Placement and the \$30.0 million upfront payment received from Lilly in August 2023 pursuant to the Lilly Agreement, will enable us to fund our operating expenses and capital expenditure requirements into 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

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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 nine months ended June 30, 2023 September 30, 2023, there were no material changes to our contractual obligations and commitments from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual obligations" in our Annual Report on Form 10-K filed with the SEC on March 2, 2023. 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, 2022 included in our Annual Report on Form 10-K filed with the SEC on March 2, 2023 for more information on our potential payment obligations under our license agreements.

On October 27, 2023, Lilly acquired the right to receive the same future milestone or royalty payments payable to Beam under the ARCLA with respect to certain development or commercial activities outside the United States or in the event Lilly does not exercise a program opt-in right.

Emerging growth company and smaller reporting company status

As an emerging growth company, or EGC, under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we may take advantage of reduced reporting requirements, including an exemption from the requirement to provide an auditor's report on internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements.

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

Based on the market value of our common stock held by non-affiliates as of June 30, 2023, we will cease to qualify as an emerging growth company, effective as of December 31, 2023, and as of such date, we will no longer be allowed to take advantage of the reduced reporting requirements that are applicable to emerging growth companies. In addition, based on the market value of our common stock held by non-affiliates as of June 30, 2023, we will no longer be able to take advantage of the various reporting and other exemptions available to smaller reporting companies beginning with our Quarterly Report on Form 10-Q for the period ending March 31, 2024. Until such time, however, we are permitted and will continue to rely on various exemptions from certain disclosure requirements as an EGC and smaller reporting company.

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 nine months ended June 30, 2023 September 30, 2023, 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 March 2, 2023.

Recently issued accounting pronouncements

See Note 2, "Summary of significant accounting policies – Recently issued accounting pronouncements" to our consolidated financial statements included in our Annual Report on Form 10-K filed with the SEC on March 2, 2023.

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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, 2023 September 30, 2023, we had cash and cash equivalents of \$70.0 million \$78.4 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, 2023 September 30, 2023, we also had marketable securities of \$392.4 million \$406.9 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 nine months ended June 30, 2023 September 30, 2023.

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, 2023** **September 30, 2023**, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended **June 30, 2023** **September 30, 2023** that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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 \$106.0 million \$151.7 million for the six nine months ended June 30, 2023 September 30, 2023 and \$157.4 million for the year ended December 31, 2022. As of June 30, 2023 September 30, 2023, we had an accumulated deficit of \$450.2 million \$496.0 million. We have no approved products and 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, 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-1 clinical trial for VERVE-101 in New Zealand and the United Kingdom, and if our investigational new drug application, or IND, is cleared, upon activation of clinical trial sites, in the United States;
- continue our current research programs and our preclinical development of product candidates, including VERVE-102 and VERVE-201;
- 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 under the Research and Collaboration Agreement, or the Lilly Agreement with Eli Lilly and Company, or Lilly, which became effective in July 2023 and seek to identify, establish and maintain additional collaborations and license agreements, and the success of those collaborations and license agreements;

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- make milestone payments to Beam Therapeutics Inc., or Beam, Lilly under our amended and restated collaboration and license agreement with Beam Therapeutics Inc., or the Beam Agreement, 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, 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 conduct our ongoing Phase 1b clinical trial of VERVE-101, complete preclinical studies of VERVE-102 and VERVE-201, continue research, development and preclinical testing, initiate additional clinical trials and potentially seek marketing approval for either VERVE-101 or VERVE-102 and VERVE-201, and any other product candidates we may develop. We expect our expenses to increase substantially in connection with our ongoing and planned activities, particularly as we advance our preclinical activities and our ongoing and planned clinical trials. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. We currently do not have a credit facility or any committed sources of capital. If we are unable to raise capital or obtain adequate funds when needed or on acceptable terms, we may be forced to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

- the progress, costs and results of our ongoing Phase 1b clinical trial of VERVE-101 and any future clinical development of VERVE-101;
- the scope, progress, results and costs of discovery, preclinical and clinical development for any product candidates we may develop;
- the 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,

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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, 2023 September 30, 2023, we had cash, cash equivalents and marketable securities of approximately \$462.5 million \$485.2 million. We believe that our existing cash, cash equivalents and marketable securities including the \$30.0 million upfront payment received from Lilly pursuant to the Lilly Agreement and the \$30.0 million received from Lilly's equity investment, will enable us to fund our operating expenses and capital expenditure requirements into 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 an early-stage clinical trial. We initiated our first clinical trial, a Phase 1b clinical trial for VERVE-101, in July 2022. Our other research programs, including for our product candidates VERVE-102 and VERVE-201, are still in the research or preclinical stage of development, and their risk of failure is high. We have not yet demonstrated our ability to complete any clinical trials, obtain marketing approvals, manufacture a clinical development or commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. In part because of this lack of experience, we cannot be certain that our ongoing preclinical studies and clinical trial will be completed on time or if the planned preclinical studies and clinical trials will begin or be completed on time, if at all. Consequently, any predictions stockholders make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing gene editing products.

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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, 2022, we had federal NOL carryforwards of \$163.9 million and state NOL carryforwards of \$148.0 million.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, a corporation that undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and research and development tax credit carryforwards to offset post-change taxable income or taxes. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced such ownership changes in the past and may experience such ownership

changes in the future as a result of subsequent changes in our stock ownership (which may be outside our control). As a result, if, and to the extent that, we earn net taxable income, our ability to use our pre-change NOLs and research and development tax credit carryforwards to offset such taxable income may be subject to limitations. Our NOLs or credits may also be impaired under state law.

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

Risks related to discovery and development

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

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

The FDA **or other regulatory agencies** **has in the past and may again in the future** require us to complete additional preclinical studies **or require us to** **and** satisfy other requests **prior to commencing clinical trials in the respective countries, which may delay for** our clinical trials, **beyond our planned timeline, causing the start or progress of such trials to be delayed.** For example, **in November 2022, the FDA has** placed our IND to conduct a clinical trial evaluating VERVE-101 in the United States on hold and **has** 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 are in the process of activating clinical trial sites in the United States. We 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 trials of VERVE-102 in the first half of 2024 or 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 any our clinical trial, trials, including with respect to VERVE-101, VERVE-102 or VERVE-201, 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 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 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.

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

We are focused on developing medicines utilizing gene editing technology, which is new and largely unproven. The base editing technologies that we have licensed and that we are utilizing with VERVE-101, 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

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data become available and we gain experience in developing gene editing therapeutics. We cannot be sure that our technologies will yield satisfactory products that are safe and effective, scalable or profitable in our initial indications or any other indication we pursue. Adverse developments in the clinical development efforts of other gene editing technology companies could adversely affect our efforts or the perception of our product candidates by investors.

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Similarly, another new gene editing technology that has not been discovered yet may be developed by third parties and may be determined to be more attractive than base editing for the gene targets that we are pursuing with base editing technology.

We also are seeking to develop 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

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programmed to carry specific DNA sequences to specific sites, without the need for making double-stranded breaks in DNA. Beam uses prime editing technology, which utilizes a CRISPR protein to target a mutation site in DNA and to nick a single strand of the target DNA. Guide RNA allows the CRISPR protein to recognize a DNA sequence that is

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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 reported clinical data from a Phase 1b trial of NTLA-2001, a CRISPR/Cas9-based gene editing product candidate for the treatment of hereditary transthyretin amyloidosis with polyneuropathy, and for the treatment of transthyretin (ATTR) amyloidosis with cardiomyopathy. 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, including the COVID-19 pandemic, may affect our ability to initiate and complete current or future preclinical studies and clinical trials, disrupt regulatory activities or have other adverse effects on our business and operations. In addition, this pandemic has adversely impacted economies worldwide, which could result in adverse effects on our business, operations and prospects.

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 COVID-19 on May 11, 2023. The FDA ended 22 COVID-19-related policies when the public health emergency ended on May 11, 2023 and is allowing 22 such policies to continue for 180 days, until November 7, 2023. The FDA had noted that it plans to retain 24 COVID-19-related policies with appropriate changes and four whose duration was not tied to the end of the public health emergency.

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 the COVID-19 pandemic will be on our business, although for the reasons described above it has the potential to adversely affect our business, financial condition, results of operations and prospects.

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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

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following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We have only initiated a clinical trial for VERVE-101 in New Zealand and the United Kingdom and are in the process of activating clinical trial sites in the United States, but 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. We received a clinical hold letter from the FDA in December 2022 that outlined the 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 including additional preclinical data relating to: (i) potency differences between human and non-human cells, (ii) risks of germline editing, and (iii) off-target analyses in non-hepatocyte cell types. The FDA also requested available clinical data from the ongoing heart-1 clinical trial. In addition, the FDA has requested that we modify the trial protocol in the United States to incorporate additional contraceptive measures and to increase the length of the staggering interval between dosing of participants.

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

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

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

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

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

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

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- 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;

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

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

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

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

authorities may not approve the price we intend to charge for our products. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

In response to the COVID-19 pandemic, the FDA issued guidance on March 18, 2020, and subsequently updated it on July 2, 2020, January 27, 2021, and August 30, 2021, to address the conduct of clinical trials during the pandemic. The guidance sets out a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical study report (or as a separate document) contingency measures implemented to manage the study, and any disruption of the study as a result of COVID-19; a list of all study participants affected by COVID-19-related study disruptions by a unique subject identifier and by investigational site, and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the study. In its most recent update to this guidance, the FDA addresses questions received during the past year from clinical practitioners who are adapting their operations in a pandemic environment. These questions focused on, among other things, when to suspend, continue or initiate a trial and how to submit changes to protocols for INDs and handle remote site monitoring visits. There is no assurance that this guidance governing clinical studies during the pandemic will remain in effect or, even if it does, that it will help address the risks and challenges enumerated above. The Biden Administration ended the public health emergency declarations related to COVID-19 on May 11, 2023. In March 2023, the FDA issued a Federal Register notice describing how the termination of the public health emergency would impact the agency's COVID-19 related guidance, including the clinical trial guidance and updates and that certain guidance would continue to be in effect past May 11, 2023. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business going forward and it has the potential to adversely affect our business, financial condition, results of operations, and prospects.

Accordingly, our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain additional financing if needed.

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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 a clinical trial in 2022. As a result, our belief in the potential capabilities of our programs is 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

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

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

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

- regulators, IRBs or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- regulators may decide that longer follow-up data are needed before they will consider our marketing application, which would delay our ability to obtain approval;
- regulators may decide the design of our clinical trials is flawed, for example if regulators do not agree with our chosen primary endpoints;
- regulators may decide to slow patient enrollment, resulting in delays to our ability to meet our timelines;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- preclinical testing may produce results based on which we may decide, or regulators may require us, to conduct additional preclinical studies before we proceed with certain clinical trials, limit the scope of our clinical trials, halt ongoing clinical trial 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.

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

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

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

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

Preclinical drug development is uncertain. Some or all of our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain marketing approvals or commercialize

these product candidates on a timely basis or at all, which would have an adverse effect on our business.

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

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

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

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

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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. In 2022, we initiated our heart-1 clinical trial for VERVE-101 in New Zealand and the United Kingdom under country-specific protocols with various modifications to eligibility in each country. Successful and timely completion of clinical trials will

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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, VERVE-102 or VERVE-201 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, VERVE-102 or VERVE-201 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.

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

Even if we are able to enroll a sufficient number of patients for our future clinical trials, we may have difficulty maintaining patients in our clinical trials. Many of the patients who end up receiving placebo may perceive that they are not receiving the product candidate being tested, and they may decide to withdraw from our clinical trials to pursue alternative therapies rather than continue the trial. If we have difficulty enrolling or maintaining a sufficient number of patients to

conduct our clinical trials, we may need to delay, limit or terminate clinical trials, any of which would harm our business, financial condition, results of operations and prospects.

If any of the product candidates we may develop, or the delivery modes we rely on to administer them, cause serious adverse events, undesirable side effects or unexpected characteristics, such 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 initiated our heart-1 clinical trial for VERVE-101 in July 2022 and have not yet completed a clinical trial. Moreover, 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

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VERVE-101. Furthermore, there has not been any gene editing product candidate that has received regulatory approval for use in humans. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. There can be no assurance that gene editing technologies will not cause undesirable side effects, as improper editing of a patient's DNA could lead to lymphoma, leukemia or other cancers or other aberrantly functioning cells.

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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.

There may be uncertainty as to the underlying cause of any such adverse event, which would make it difficult to accurately predict side effects in ongoing or future clinical trials and would result in significant delays in our programs.

Our GalNAc-LNPs, which we plan to use in VERVE-102 and VERVE-201, are a novel delivery mechanism for delivery of gene editors to the liver and have not yet been studied in humans.

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

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

Adverse public perception of genetic medicines, and gene editing and base editing in particular, may negatively impact 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. For example, in 2003, trials using early versions of murine gamma-retroviral vectors, which integrate with, and thereby alter, the host cell's DNA, have led to several well-publicized adverse events, including

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

From time to time, we may publish or report interim or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available. 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.

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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

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facilities also could restrict our ability to ensure sufficient clinical material for any clinical trials we may be conducting or are planning to conduct and meet market demand for any product candidates we develop and commercialize.

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

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one

or more of our product candidates receives regulatory approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:

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

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

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

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

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

We are conducting and plan to conduct one or more additional clinical trials with one or more trial sites that are located outside the United States, including our ongoing Phase 1b trial of VERVE-101 which is being conducted at trial sites in New Zealand and the United Kingdom. Although the FDA may accept data from clinical trials conducted outside the United

States, acceptance of these data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with ethical principles. The

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FDA must be able to validate the data from the trial through an onsite inspection, if necessary. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the

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applicable local laws, whether the FDA accepts the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates.

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

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

Risks related to our dependence on third parties

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

We do not expect to independently conduct all aspects of our product manufacturing, research and preclinical and clinical testing. We currently rely, and expect to continue to rely, on third parties with respect to many of these items, including CMOs for the manufacturing of any product candidates we test in preclinical or clinical development, as well as CROs for the conduct of our clinical trial, 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

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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.

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

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of VERVE-101 and our other product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. We also

rely on these third parties for packaging, labeling, sterilization, storage, distribution and other production logistics. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

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

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

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

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

results of operations and cause potential reputational damage. Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we

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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

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costs and delays in identifying and qualifying any such replacement or be unable to reach agreement with an alternative manufacturer.

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

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

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

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

As part of our strategy, we have entered into collaborations and intend to seek to enter into additional collaborations with third parties for one or more of our programs or product candidates. For example, in April 2019, we entered into the **Beam Agreement** **ARCLA** 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; 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-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 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 Beam Agreement, and we may have under any other arrangements that we may enter into with any third parties, limited control over the amount and timing of resources that collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements may depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

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

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

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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;

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- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates on a discretionary basis;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

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

Collaboration agreements may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. For example, upon execution of the Beam Agreement, we issued 276,075 shares of our common stock to Beam; 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 high nine-digit dollar amount to \$10.0 billion, or sale of our company for consideration in excess of those thresholds. In the event of a change of control of our company or a sale of our company,

we are required to pay any related success payment in cash within a specified period following such event. Otherwise, the success payments may be settled at our option in either cash or shares of our common stock, or a combination of cash and shares of our common stock. In September 2021, we notified Harvard and Broad that our average market capitalization exceeded three specified thresholds as of a relevant measurement date and

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aggregate success payments of approximately \$6.3 million became payable under the Cas9 License Agreement, which we settled in cash in November 2021.

We could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of several factors. If we license rights to any product candidates we or our

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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

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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

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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

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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

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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 Beam Agreement, the Cas9 License Agreement, the Acuitas Agreement, the Novartis Agreement, and other license agreements, pursuant to which we in-license and have acquired key patents and patent applications for our gene editing technology, LNP technology and product candidates. These license agreements impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate our license, in which event we would not be able to develop or market our gene editing technology or product candidates covered by the intellectual property licensed under these agreements.

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

preexisting rights held by the licensor or certain third parties. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in certain territories or fields. If we determine that rights to such

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

In addition, pursuant to the Cas9 License Agreement, under certain specific circumstances, Harvard and Broad may grant a license to the patents that are the subject of such license agreements to a third party in the same field as such patents

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

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

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

Furthermore, inventions contained within some of our in-licensed patents and patent applications were made using U.S. government funding. We rely on our licensors to ensure compliance with applicable obligations arising from such funding, such as timely reporting, an obligation associated with our in-licensed patents and patent applications. The failure of our licensors to meet their obligations may lead to a loss of rights or the unenforceability of relevant patents. For example, the

U.S. government could have certain rights in such in-licensed patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. If the U.S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The U.S. government's rights may also permit it to disclose the funded inventions and technology to third parties and to exercise march-in rights to use or allow third parties to use the technology we have licensed that was developed using U.S. government funding. The U.S. government may also exercise its march-in rights if it determines that action is necessary because we or our licensors failed to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in such in-licensed U.S. government-funded inventions may be subject to certain requirements to manufacture product candidates embodying such inventions in the United States. Any of the foregoing could harm our business, financial condition, results of operations and prospects significantly.

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

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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,

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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 that are co-owned by the Boston Licensing Parties), 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.

There can be no assurance that the current appeal or these pending U.S. interference proceedings will be 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.

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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

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

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

We are party to agreements, and we may enter into additional arrangements, with third parties that may impose diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. We have existing agreements, pursuant to which we are obligated to pay royalties on net product sales of product candidates or related technologies to the extent they are covered by the agreements. If we fail to comply with such obligations under current or future agreements, our counterparties may have the right to terminate these agreements or require us to grant

them certain rights. Such an occurrence could materially adversely affect the value of any product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects. While we still face all of the risks described herein with respect to those agreements, we cannot prevent third parties from also accessing those technologies. In addition, our licenses may place restrictions on our future business opportunities.

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

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

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

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the intellectual property or intellectual property rights we in-license. If other third parties have ownership rights to intellectual property or intellectual property rights we in-license, they may be able to license such intellectual property or intellectual property 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 in 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

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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

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investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our gene editing technology and product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of therapies, products or their methods of use or manufacture. We are aware of certain third-party patent applications that, if issued, may be construed

to cover our gene editing technology and product candidates. There may also be third-party patents of which we are currently unaware with claims to technologies, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

It is possible that we have failed to identify relevant third-party patents or applications that our product candidates and programs may infringe. Because patent applications can take many years to issue, may be confidential for 18 months or more after filing and can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use, sale or importation of any product candidates we may develop or our technology, and we may not be aware of such patents. Furthermore, applications filed before November 29, 2000

November 29, 2000 and certain applications filed after that date that will not be filed outside the United States may remain confidential until a patent issues. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to any product candidates we may develop and our technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, any product candidates we may develop or the use of any product candidates we may develop.

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

Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. Our product candidates make use of CRISPR-based gene editing technology, which is a field that is highly active for patent filings. The extensive patent filings related to CRISPR and Cas make it difficult for us to

assess the full extent of relevant patents and pending applications that may cover our gene editing technology and product candidates and their use or manufacture. There may be third-party patents or patent applications, including patents held or controlled by our competitors with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our gene editing technology and product candidates.

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

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

Patents have a limited lifespan. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Various extensions may be available, but the life of

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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

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

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

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

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

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

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

extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

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

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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.

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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

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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

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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

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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

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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.

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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.

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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 AG, is approved in the United States for the treatment of patients with clinical ASCVD or HeFH who require additional lowering of LDL-C and in Europe for the treatment of patients with hypercholesterolemia, including HeFH, or mixed dyslipidemia. Inclisiran acts by inhibiting the synthesis of PCSK9 within liver cells, which is distinct from extracellular protein inhibition. We are also aware of **three** **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 include MK-0616 from Merck & Co., Inc, for which Merck recently released data from a completed Phase 2b trial of adult patients with hypercholesterolemia and **announced plans to initiate** **initiated** a Phase 3 pivotal **study** **trial of adult patients with hypercholesterolemia** in the second half of **August** 2023; **an oral small molecule from Serometrix LLC in-** **licensed by Esperion Therapeutics, which disclosed plans in 2022 to submit an IND in late 2024 or early 2025;** and AZD0780, acquired by AstraZeneca from Dogma Therapeutics, which is being evaluated in an ongoing Phase 1 clinical trial.

We are aware of two other gene 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.

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 ARO-ANG3, a siRNA targeting ANGPTL3 being evaluated by Arrowhead Pharmaceuticals in Phase 2 clinical trials of patients with HoFH and patients with mixed dyslipidemia. In 2022, Arrowhead announced plans to initiate pivotal Phase 3 studies of ARO-ANG3 in patients with HoFH and patients with HeFH in the second half of 2023. In addition, Lilly is evaluating a siRNA targeting ANGPTL3 protein in a Phase 2 study in adults with mixed dyslipidemia, and in 2022, CRISPR announced CTX310, its gene editing program targeting ANGPTL3, which is in IND-enabling studies with plans for initial patient dosing in 2023.

Several investigational medicines designed to reduce lipoprotein(a), or Lp(a), are currently in development. These include **pelecarsen**, **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 high Lp(a) and cardiovascular disease, with topline results expected in 2025. Olpasiran is an investigational siRNA medicine targeting *LPA* licensed by Amgen from Arrowhead Pharmaceuticals, which was recently shown to lower Lp(a) concentrations in patients with

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established ASCVD and high Lp(a) concentrations. The potential for Olpasiran to reduce cardiovascular events in patients with

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existing ASCVD and high Lp(a) will be evaluated in the Phase 3 OCEAN(a) study, which was initiated in 2022 with plans for study completion in 2026. In addition, SLN360 is an investigational siRNA medicine being developed by Silence Therapeutics plc that is being evaluated in an ongoing Phase 2 study of patients with high Lp(a) concentrations and high risk for ASCVD events with topline results expected in the fourth quarter of 2023, and, in 2022, CRISPR announced CTX320, its research preclinical stage *in vivo* 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

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entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do

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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, the 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.

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

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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. 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.

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

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

- economic weakness, including inflation, or political instability in particular economies and markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;

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

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

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

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

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

We currently do not hold any clinical trial liability insurance coverage. We may need to obtain insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is

increasingly expensive. We may not be able to obtain and maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful clinical trial or product liability claim or series of

claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Risks related to regulatory approval and other legal compliance matters

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

The regulatory requirements that will govern any novel gene editing product candidates we develop are not entirely clear and may change. Within the broader genetic medicines field, we are aware of a limited number of gene therapy products that have received marketing authorization from the FDA and the EMA. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. Regulatory requirements governing gene therapy products and cell therapy products have changed frequently and will likely continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials may also be subject to review and oversight by an IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

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

Adverse developments in post-marketing experience or in clinical trials conducted by others of gene therapy products, cell therapy products, or products developed through the application of a base editing or other gene editing technology may cause the FDA, the EMA, and other regulatory bodies to revise the requirements for development or approval of any

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

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

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

During the regulatory review process, we will need to identify success criteria and endpoints such that the FDA, the EMA, or other regulatory authorities will be able to determine the clinical efficacy and safety profile of any product candidates we

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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. No gene editing therapeutic product has been approved in the United States or in Europe.

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

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

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

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

Obtaining and maintaining marketing approval or commercialization of our product candidates in the United States does not mean that we will be successful in obtaining marketing approval of our product candidates in other jurisdictions. Failure to obtain marketing approval in foreign jurisdictions would prevent any product

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candidates we develop from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.

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

As a result of the United Kingdom's withdrawal from the European Union, or Brexit, the MHRA is now the sole decision maker for marketing authorizations of pharmaceutical products in the United Kingdom, except for Northern Ireland. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law of the United Kingdom the body of European Union law governing medicinal products that pre-existed before the United Kingdom's withdrawal from the European Union.

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

submit a separate application to the MHRA for marketing approval in the United Kingdom, in addition to any planned marketing authorization applications for the EMA.

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

We may seek certain designations for our product candidates, including Fast Track, Breakthrough Therapy, Regenerative Medicine Advanced Therapy and Priority Review designations in the United States, 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

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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 on February 14, 2023, 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 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.

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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 on December 27, 2020, the requirement for a product to show clinical superiority applies to drugs and biologics that received orphan drug designation before enactment of FDARA in 2017, but have not yet been approved or licensed by FDA.

The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term “same disease or condition” means the designated “rare disease or condition” and could not be interpreted by the FDA to mean the “indication or use.” Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 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, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The FDA typically advises that patients treated with genetic medicine undergo follow-up observations for potential adverse events for up to a 15-year period. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

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

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

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

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

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

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

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown

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occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

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

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

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws impose civil and criminal penalties against individuals or entities for knowingly presenting or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other government payers that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as further amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, which imposes certain requirements, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of such individually identifiable health information;
- the federal transparency requirements under the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services, or HHS, information related to payments and other transfers of value to physicians, as defined by such law, and teaching hospitals and other covered recipients and ownership and investment interests held by 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 went into effect in April 2013 and will remain in effect through 2031. Pursuant to the CARES Act and subsequent legislation, these Medicare sequester reductions were suspended through the end of June 2022, but the full 2% cut resumed thereafter on July 1, 2022. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These 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.

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Since enactment of the PPACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, the Tax Act repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the PPACA is an essential and inseparable feature of the PPACA, and therefore because the mandate was repealed as part of the Tax Act, the remaining provisions of the PPACA are invalid as well. However, on June 17, 2021, the U.S. Supreme Court dismissed the case and sustained the PPACA. Litigation and legislation over the PPACA are likely to continue, with unpredictable and uncertain results.

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

programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the PPACA; and policies that reduce affordability of coverage or financial assistance, including for dependents. This Executive Order also directs the HHS to create a special enrollment period for the Health Insurance Marketplace in response to the COVID-19 pandemic.

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

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

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs 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, on December 29, 2021, the Centers for Medicare & Medicaid Services, or 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, or SIP, to import certain prescription drugs from Canada into the United States. The final rule is currently the subject of ongoing litigation, but at least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada with the intent of developing SIPs for review and approval by the FDA. 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 (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 new 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.

Pharmaceutical companies and other parties have recently filed lawsuits in various courts with constitutional claims against HHS and CMS. 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. 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.

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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 agent—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.

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In addition to California, at least eleven 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 before the end of 2026. 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. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2023 legislative sessions that will go into effect in 2024 and beyond, including New York and New Jersey. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partners’ or service providers’ privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total

worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR places restrictions on the cross-border transfer of personal data from the European Union to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the European Union to other countries. In July 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU's decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-U.S. Privacy Shield. The European Commission initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022, and the European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision will permit 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 UK's Data Protection Act and the GDPR, respectively. The United Kingdom and the United States are also in discussions to develop a US-UK "data bridge", which would function similarly to the EU-US Data Privacy Framework and provide 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,

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manufacturing, or selling certain drugs and drug candidates outside of the United States, which could limit our growth potential and increase our development costs.

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

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

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

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

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

Risks related to employee matters and managing growth

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

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

The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize products. Competition to hire from this limited pool is

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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.

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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 ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our or our vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position and reputation could be harmed and the further development and commercialization of our product candidates could be delayed. As a result of such an event, we may be in breach of our contractual obligations. Furthermore, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us

to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

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

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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.

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

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

Our executive officers and directors and their affiliates, in the aggregate, beneficially owned shares representing approximately 21.1% 21.3% of our common stock as of August 3, 2023 October 31, 2023. As a result, if these stockholders were to choose to act together, they would effectively be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, could significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of ownership control may:

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

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

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby

depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

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

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

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

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

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

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analysts will provide favorable coverage.

Although we have obtained analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, or provides more favorable relative recommendations about our competitors, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

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

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

- timing and results of or developments in preclinical studies and clinical trials of our product candidates or those of our competitors or potential collaborators;
- adverse regulatory decisions, including failure to receive regulatory approvals for any of our product candidates;
- our success in commercializing our product candidates, if and when approved;
- developments with respect to competitive products or technologies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license products, product candidates, technologies, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- sales of common stock by us, our executive officers, directors or principal stockholders, or others;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, such as the impact of the COVID-19 pandemic on our industry and market conditions; 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 additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Moreover, holders of a substantial number of shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also filed 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 will no longer qualify as an “emerging growth company” or a “smaller reporting company” as of December 31, 2023 and, as a result, we will no longer be able to avail ourselves of certain reduced disclosure requirements applicable to emerging growth companies and/or smaller reporting companies.

We are currently an “emerging growth company,” or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include:

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

We are also currently a “smaller reporting company,” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Similar to EGCs, smaller reporting companies have reduced disclosure obligations, such as an ability to provide simplified executive compensation information and only two years of audited financial statements in an annual report on Form 10-K, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure.

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

In addition, the JOBS Act permits an EGC to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to “opt out” of such extended transition period, which means that when a standard is

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issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an EGC or a smaller reporting company.

Based on the market value of our common stock held by non-affiliates as of June 30, 2023, **will**, **we will** cease to qualify as an EGC as of December 31, 2023, and as such, we will no longer be able to take advantage of any of the exemptions from various reporting requirements that are applicable to EGCs effective as of December 31, 2023. In addition, based on the market value of our common stock held by non-affiliates as of June 30, 2023, we will no longer be able to take advantage of

any of the exemptions from various reporting requirements that are applicable to smaller reporting companies beginning with our quarterly report on Form 10-Q for the quarter ending March 31, 2024. We expect that the loss of our EGC and smaller reporting company status and compliance with these additional requirements will substantially increase our legal and financial compliance costs. In addition, any failure to comply with these additional requirements in a timely manner, or at all, could have an adverse effect on our business and results of operations and could cause a decline in the price of our common stock.

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

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

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

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our annual report required to be filed with the SEC for the fiscal year ending December 31, 2023. At such time as we are required to obtain auditor attestation, if we then 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. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and

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

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

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

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

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

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholder 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.

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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 eliminates the option to deduct research and development expenditures currently and generally requires corporations to capitalize and amortize them over five years.

In addition to the CARES Act, as part of Congress' response to the COVID-19 pandemic, economic relief legislation has been enacted in 2020 and 2021 containing tax provisions, 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, and use of proceeds, and issuer purchases of equity securities.

Recent sales of unregistered securities

None. 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, 2023 September 30, 2023, 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 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† | <u>Research and Collaboration Agreement, dated June 14, 2023, by and between the Registrant and Eli Lilly and Company, Company (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2023)</u> |
| 10.2† | <u>Stock Purchase Agreement, dated June 14, 2023, by and between the Registrant and Eli Lilly and Company, Company (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2023).</u> |
| 31.1* | <u>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.</u> |
| 31.2* | <u>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.</u> |
| 32.1+ | <u>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.</u> |
| 32.2+ | <u>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.</u> |
| 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.

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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 10, 2023 November 7, 2023

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

Date: August 10, 2023 November 7, 2023

By: /s/ Allison Dorval
Allison Dorval
Chief Financial Officer
Principal Financial and Accounting Officer

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Exhibit 10.1

Execution Version

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.

RESEARCH AND COLLABORATION AGREEMENT

between

VERVE THERAPEUTICS, INC.

and

ELI LILLY AND COMPANY

Dated as of June 14, 2023

RESEARCH AND COLLABORATION AGREEMENT

This Research and Collaboration Agreement (this “**Agreement**”) is made and entered into as of June 14, 2023 (the “**Execution Date**”) by and between Verve Therapeutics, Inc., a Delaware corporation (“**Verve**”), and Eli Lilly and Company, an Indiana corporation (“**Lilly**”). Verve and Lilly are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

RECITALS

WHEREAS, Verve owns and controls certain intellectual property rights with respect to gene editing products and technology and expertise in the development and manufacturing of gene editing products;

WHEREAS, Lilly and its Affiliates (defined below) have expertise in the research, development, manufacturing and commercialization of pharmaceutical products;

WHEREAS, the Parties wish to collaborate on certain activities aimed at research and development of Licensed Products (defined below) in accordance with the terms set forth below; and

WHEREAS, Verve wishes to grant to Lilly, and Lilly wishes to obtain, exclusive licenses under certain of Verve’s intellectual property rights to Exploit (defined below) Licensed Products, in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE 1

DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the meanings set forth in this Article 1:

1.1. "Accounting Standards" means, with respect to a Party or any of its Affiliates or its or their Sublicensees, United States Generally Accepted Accounting Principles (**U.S. GAAP**), consistently applied.

1.2. "Acquired Verve-Controlled Affiliate" has the meaning set forth in Section 9.2.

1.3. "Acquirer" has the meaning set forth in Section 1.26.

1.4. "Active Development" means that Lilly, its Affiliates or its Sublicensees, are actively engaged in one or more of the following activities for a Licensed Product during the period from Phase 2 Assumption until Regulatory Approval: **[**]**.

1.5. "Additional Target" means a **[**]** Option Target incorporated into the Research and Development Program pursuant to Section 2.4.

1.6. "Additional Target Election Period" has the meaning set forth in Section 2.4.

1.7. "Affiliate" means, with respect to any Person, any entity that, at the relevant time (whether as of the Effective Date or thereafter), directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Person, for so long as such control exists. As used in this Section 1.7, "control" means: (a) to possess, directly or indirectly, the power to direct or cause the direction of the management or policies of an entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) direct or indirect ownership of fifty percent (50%) (or such lesser percentage that is the maximum allowed to be owned by a foreign entity in a particular jurisdiction) or more of the voting share capital or other equity interest in such entity. **[**]**.

1.8. "Alliance Manager" has the meaning set forth in Section 7.4.

1.9. "Applicable Laws" means the applicable provisions of any and all federal, national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, guidelines or requirements, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, or permits of or from any court, arbitrator, Regulatory Authority, Governmental Authority, taxing authority, national securities exchange or exchange listing organization having jurisdiction over or related to the relevant subject item that may be in effect from time to time during the Term, including data protection and privacy laws.

1.10. "Background IP" means, with respect to Lilly, the Lilly Background IP and, with respect to Verve, the Verve Background IP.

1.11. "[]"** has the meaning set forth in Section [**].

1.12. "[]"** has the meaning set forth in Section [**].

1.13. "Biosimilar Application" has the meaning set forth in Section 11.9.6.

1.14. "BLA" means a Biologics License Application as described in 21 C.F.R. 601.2 or an equivalent application in any other applicable jurisdiction in the Territory.

1.15. "[] Agreement"** means the [**] License Agreement by and between [**] and Verve, dated as of [**], as such agreement may be amended from time to time in accordance with its terms.

1.16. "Budget Date" has the meaning set forth in Section 6.5.

1.17. "Budgeted Research and Development Expenditures" has the meaning set forth in Section 3.4.3(b).

1.18. "Business Day" means any day, other than any Saturday, Sunday, a U.S. Federal holiday, or any day that banks are authorized or required to be closed in Indianapolis, Indiana, New York, New York or Boston, Massachusetts.

1.19. "Calendar Quarter" means each respective period of three (3) consecutive

months ending on March 31, June 30, September 30, and December 31 of any Calendar Year; except that the first Calendar Quarter will begin on the Effective Date and the last Calendar Quarter will end on the last day of the Term.

1.20. "Calendar Year" means each respective period of twelve (12) consecutive months beginning on January 1 and ending on December 31 of each year; except that the first Calendar Year will begin on the Effective Date and the last Calendar Year will end on the last day of the Term.

1.21. "Calendar Year Net Sales" means, with respect to any Licensed Product, the aggregate, worldwide Net Sales of such Licensed Product of Lilly, its Affiliates and Sublicensees in a single Calendar Year.

1.22. "Candidate" means a Development Molecule that has achieved Candidate Selection, or which Lilly has otherwise elected to progress in accordance with Section 3.2.

1.23. "Candidate Selection" has the meaning set forth in Section 3.2.

1.24. "Candidate Selection Critical Success Factors" means the criteria to achieve Candidate Selection, as set forth in the applicable Research and Development Plan.

1.25. "Candidate Selection Data Package" means, with respect to a given Licensed Program, a data package containing the Program Results required to be delivered under the corresponding Research and Development Plan in association with a notification that the Candidate Selection Critical Success Factors are satisfied pursuant to Section 3.2.

1.26. "Change of Control" means, with respect to either Party: (a) the acquisition by a Third Party, in one transaction or a series of related transactions, of direct or indirect beneficial ownership of more than fifty percent (50%) of the outstanding voting equity securities of such Party; (b) a merger or consolidation involving such Party, as a result of which a Third Party acquires direct or indirect beneficial ownership of more than fifty percent (50%) of the voting power of the surviving entity immediately after such merger, reorganization or consolidation; (c) a sale of all or substantially all of the assets of such Party in one transaction or a series of related transactions to a Third Party; (d) the acquisition by a Third Party of majority control of the board of directors or equivalent governing body of such Party; or (e) the acquisition by a Third Party of all or substantially all of the assets of such Party related to the transactions contemplated by this Agreement. The acquiring or combining Third Party referenced in any of (a)-(e), and any of such Third Party's Affiliates (whether in existence as of or at any time following the applicable transaction, but other than the acquired Party and its Affiliates as in existence prior to the applicable transaction, or Affiliates the acquired Party controls after the applicable transaction) are referred to collectively herein as the **"Acquirer"**.

1.27. "Claim" has the meaning set forth in Section 13.1.1.

1.28. "Clinical Trial" means any human clinical study of a pharmaceutical product including for clarity any post-Regulatory Approval clinical trial.

1.29. "CMC" means chemistry, manufacturing and controls.

1.30. "CMO" means a Third Party contract manufacturing organization.

1.31. "Code" has the meaning set forth in Section 16.8.

1.32. "Co-Funded Product" means, during the Cost-Sharing Term, a Licensed Product that is subject to Expense and Margin Sharing.

1.33. "Co-Funded Product Divestment" has the meaning set forth in Section 6.8.

1.34. "Co-Funded Product Divestment Effective Date" has the meaning set forth in Section 6.8.

1.35. "Co-Funded Product Sharing Amounts" has the meaning set forth in Section 10.5.5(c).

1.36. "Combination Licensed Product" has the meaning set forth in Section 1.151.

1.37. "Commercial Milestone Event" has the meaning set forth in Section 10.3.2.

1.38. "Commercial Milestone Payment" has the meaning set forth in Section 10.3.2.

1.39. "Commercialization" means (a) the offering for sale of, or sale of a Licensed Product, or (b) conducting activities, other than Research, Development or Manufacturing, in preparation for or in furtherance of the foregoing activities; in each case, including activities related to marketing, promoting, distributing, importing, pricing and recording sales of such Licensed Product. When used as a verb, **"to Commercialize"** and **"Commercializing"** mean to engage in Commercialization, and **"Commercialized"** has a corresponding meaning.

1.40. "Commercially Reasonable Efforts" of a Party means that level of efforts and resources [**]. For clarity, "Commercially Reasonable Efforts" shall be determined on an indication-by-indication, product-by-product, and country-by-country basis within the Territory, and it is anticipated that the level of effort for different indications, products and countries may differ and may change over time, reflecting changes in the status of the compound, product or therapy and the indications and country(ies) involved.

1.41. “Competing Product” means any *in vivo* genome-editing product (excluding a Licensed Product) in the Field that is Directed To (a) during the Research Term, the Initial Target or any **[**]** Option Target excluding an Expired **[**]** Option Target, and (b) following expiration of the Research Term, any Licensed Target. For purposes of this definition of Competing Product, a genome-editing product is not considered Directed To a Target unless **[**]**.

1.42. “Competing Program” means activities in furtherance of Exploitation of a Competing Product; provided, however, that Research and Development activities that lead to the unintentional discovery, Research or Development of a Competing Product shall not be considered to have been conducted in furtherance of Exploitation of a Competing Product provided conduct of such activities cease immediately following the discovery thereof.

1.43. “Completion” means, with respect to a Clinical Trial, **[**]** after the publication of the final clinical study report for such Clinical Trial.

1.44. “Confidential Proprietary Information” has the meaning set forth in Section 14.1.1.

1.45. “Confidentiality Agreement” means that certain Confidentiality Agreement between Lilly and Verve, dated as of **[**]**, as amended by Lilly and Verve pursuant to the First Amendment to the Confidentiality Agreement, dated as of **[**]**.

1.46. “Control” means, with respect to any Know-How or Patent, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise (other than by any license granted under this Agreement), to grant a license, sublicense, or other right to or under such Know-How or Patent as provided for herein without violating the terms of any agreement with any Third Party. Notwithstanding the foregoing: (a) any Know-How or Patent that is in-licensed or acquired by Verve or its Affiliates under a Future In-Licensed Technology Agreement shall not be deemed “Controlled” by Verve or its Affiliates unless and until Lilly agrees to take a sublicense under such Future In-Licensed Technology Agreement in accordance with Section 11.7.2; and (b) Verve or its Affiliates will be deemed to not Control any Know-How or Patent of an Acquirer that (i) either (A) is Controlled by the Acquirer as of the closing of the Change of Control pursuant to which such Acquirer became an Affiliate of Verve or (B) after the closing of such Change of Control, is generated or acquired by the Acquirer without access or use of (I) any of Lilly’s Confidential Proprietary Information or non-public Lilly Sole IP, (II) any non-public Licensed Know-How (except pursuant to a license granted prior the closing of such Change of Control for activities not Directed To a Licensed Target), (III) any non-public Verve Sole IP generated in the conduct of activities under this Agreement (except pursuant to a license granted prior the closing of such Change of Control for activities not Directed To a Licensed Target), or (IV) information received through violation of a Firewall, and (ii) such any Know-How or Patent of the

Acquirer is not used or practiced by or on behalf of Verve or any of its Affiliates in the performance of activities under this Agreement.

1.47. "Cost Overages" has the meaning set forth in [Section 3.4.2](#).

1.48. "Cost-Sharing Election Periods" has the meaning set forth in [Section 6.1](#).

1.49. "Cost-Sharing Fee" has the meaning set forth in [Section 6.3](#).

1.50. "Cost-Sharing Option" has the meaning set forth in [Section 6.1](#).

1.51. "Cost-Sharing Option Effective Date" means, with respect to any Co-Funded Product, **[**]** following (a) **[**]** or (b) **[**]**.

1.52. "Cost-Sharing Option Information Package" has the meaning set forth in [Section 6.1](#).

1.53. "Cost-Sharing Requirements" means that, at the time Verve submits notice expressing intent to exercise the Cost-Sharing Option pursuant to [Section 6.1](#), Verve has, or has a reasonable expectation of, **[**]**.

1.54. "Cost-Sharing Term" means, with respect to a Co-Funded Product, the period beginning on the Cost-Sharing Option Effective Date for such Co-Funded Product and ending upon the earliest to occur of: (a) a Lilly Cost-Sharing COC Termination; (b) the effective date of termination for a Co-Funded Product by Lilly pursuant to [Section 16.3](#); (c) the effective date of termination of the Cost-Sharing Term by Verve pursuant to [Section 6.7](#); (d) the Co-Funded Product Divestment Effective Date; and (e) the effective date of termination of the Cost-Sharing Term by Lilly pursuant to [Section 6.9](#).

1.55. "Cost-Sharing Wind-Down Period" has the meaning set forth in [Section 6.9](#).

1.56. "Cover" or "Covering" means, with respect to a claim of a Patent and (a) a Licensed Product, that such claim would be infringed, absent a license, by the Exploitation of such Licensed Product (considering claims of patent applications to be issued as then pending); (b) a Verve Gene Editor, that such claim would be infringed, absent a license, by the Exploitation of such Verve Gene Editor (considering claims of patent applications to be issued as then pending); or (c) a Verve Delivery Element, that such claim would be infringed, absent a license, by the Exploitation of such Verve Delivery Element (considering claims of patent applications to be issued as then pending).

1.57. “Development” or “Develop” means any and all activities directed to the non-clinical and clinical drug development activities that are necessary or useful to obtain Regulatory Approval for a Licensed Product, or other compound, product or therapy, including design and conduct of pre-BLA approval clinical trials and the preparation and filing of Regulatory Filings and all regulatory affairs related to the foregoing. When used as a verb, **“Developing”** means to engage in Development and **“Developed”** has a corresponding meaning.

1.58. “Development Advancement” has the meaning set forth in [Section 4.2](#).

1.59. “Development Costs” means, with respect to a Co-Funded Product (or components thereof), the following the [**]:

[**];

in each case (1.59.1 through 1.59.7), to the extent such costs are calculated in accordance with Accounting Standards and incurred by a Party either (x) during the Cost-Sharing Term or (y) in the [**] period prior to the applicable Cost-Sharing Option Effective Date primarily in furtherance of Phase 2 Clinical Trials or later activities for such Co-Funded Product. Notwithstanding anything to the contrary set forth in this Agreement, “Development Costs” in all cases will exclude [**].

1.60. “Development Molecule” means any *in vivo* genome editing product that: (a) is the subject of activities under a Research and Development Plan; (b) incorporates a Verve [**] Element; and (c) is Directed To a Licensed Target.

1.61. “Directed To” means, with respect to an *in vivo* genome editing product and a Target, that such *in vivo* genome editing product contains a gene editor that: (a) [**]; and (b) [**].

1.62. “Disclosing Party” has the meaning set forth in [Section 14.1.2](#).

1.63. “Dispute” has the meaning set forth in [Section 17.2](#).

1.64. “Divestiture” means, [**].

1.65. “DOJ” has the meaning set forth in [Section 15.1](#).

1.66. “[]”** means, [**].

1.67. “Effective Date” means the HSR Clearance Date if and when such date occurs.

1.68. “Eli Lilly and Company Animal Care and Use Requirements for Animal Researchers and Suppliers” has the meaning set forth in Section 3.7.

1.69. “Eli Lilly and Company Good Research Practices” has the meaning set forth in Section 3.7.

1.70. “Eligible Cost” means with respect to a Co-Funded Product, to the extent incurred during the Cost-Sharing Term and in accordance with this Agreement [**]:

(a) [**].

Notwithstanding anything to the contrary set forth above, “Eligible Costs” are exclusive of and do not include [**] or any cost for which a Party is solely responsible under this Agreement. Except to the extent already included in Internal Qualified Expenses, “Eligible Costs” shall not include either Party’s costs [**].

1.71. “Escalation” has the meaning set forth in Section 17.2.

1.72. “EU Major Markets” means [**].

1.73. “Executive Officers” means (a) with respect to Verve, Verve’s [**] and (b) with respect to Lilly, the [**] (or substantially equivalent function within Lilly); or, in each case (a) and (b), his or her designee that has authority to decide the matter at hand.

1.74. “Existing In-Licensed Technology” means any Patent or Know-How Controlled by a Third Party that: (a) with respect to Patents, [**]; or (b) with respect to Know-How, [**]; in each case ((a) and (b)) as applicable to a Development Molecule that is the subject of the Research and Development Plan attached hereto as Schedule 2.6.1. The Existing In-Licensed Technology is described in Schedule 1.74. Notwithstanding the foregoing, the Patents and Know-How licensed under the [**] Agreement shall not constitute Existing In-Licensed Technology.

1.75. “Existing In-License Agreement” means the Third Party agreements pursuant to which Verve licenses any Existing In-Licensed Technology.

1.76. “Existing License Share” has the meaning set forth in Section 11.7.1.

1.77. “Existing Patents” has the meaning set forth in Section 12.2.3(a).

1.78. “Expense and Margin Sharing” has the meaning set forth in Section 10.5.

1.79. “Expired [] Option Target”** has the meaning set forth in Section [**].

1.80. “Exploit” means to make, have made, use, have used, import, sell, and offer for sale, including to Research, Develop, Manufacture, and Commercialize, and **“Exploitation”** means the act of Exploiting.

1.81. “Field” means the diagnosis, prevention and treatment of any and all diseases in humans and non-human animals.

1.82. “Firewall Event” has the meaning set forth in Section 18.8.5.

1.83. “Firewall Period” means, [**].

1.84. “Firewalls” means reasonable and appropriate technical, physical and procedural safeguards established by Verve and any Acquirer of Verve which has a Competing Program: (a) to ensure that no non-public information or materials (such as [**]), or other non-personnel resources directly relating to Licensed Products or non-public Licensed Know-How are accessible by personnel of the Acquirer working on the Competing Program during the Firewall Period (excluding [**]); and (b) where such Acquirer is also a Lilly Competitor, to ensure that no Confidential Proprietary Information of Lilly is accessible by personnel of the Acquirer. Notwithstanding the foregoing, Verve shall not have the obligation under clause (a) to prevent access to information, materials, or other non-personnel resources relating to Licensed Know-How by personnel of an Acquirer of Verve that, before the closing of the applicable Change of Control, had a license to such Licensed Know-How from Verve for activities not Directed to a Licensed Target.

1.85. “First Commercial Sale” means the [**].

1.86. “First Tox Dose” means the first dosing of the first animal in a GLP Toxicology Study with respect to any Licensed Product or Candidate.

1.87. “FTC” has the meaning set forth in Section 15.1.

1.88. “FTE” means the equivalent of a full-time employee’s work performing Research, Development or Commercialization activities under this Agreement performing [**] work hours per Calendar Year. If any such individual works partially on Research, Development or Commercialization activities under this Agreement and partially on other work in a Calendar Quarter, then the “FTE” to be attributed to such individual’s work hereunder shall be calculated based upon the percentage of such individual’s total work time in such Calendar Quarter that such individual spent conducting Research, Development or Commercialization activities under this Agreement based on [**] working hours per Calendar Year, applied consistently throughout the Calendar Year. Overtime, and work on weekends, holidays and the like will not be counted

with any multiplier (e.g., time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. Notwithstanding anything to the contrary in the foregoing, no individual person can ever constitute more than a single FTE.

1.89. "FTE Rate" means the rate of FTE costs incurred by a Party, which for the purposes of this Agreement is deemed to be \$[**] per FTE per Calendar Year through Calendar Year 2023 and which shall be increased (or decreased) each subsequent Calendar Year by the percentage change in the Producer Price Index – Pharmaceutical Preparation Manufacturing from the prior year. The FTE Rate includes costs of salaries, benefits, supplies, and other employee costs, and supporting overhead and administrative allocations.

1.90. "Future In-Licensed Technology" means any Patents and Know-How Controlled by a Third Party that: (a) (i) with respect to Patents, [**] or (ii) with respect to Know-How, [**]; and (b) is Controlled by Verve after the Effective Date pursuant to a license from a Third Party.

1.91. "Future In-Licensed Technology Agreement" means an agreement pursuant to which Verve acquires a license to Future In-Licensed Technology from a Third Party.

1.92. "Generate" means: (a) with respect to any Know-How constituting an invention, to invent; (b) with respect to any Know-How constituting data, to collect, compile or document; and (c) with respect to any other Know-How, to create, develop or discover. **"Generation"** and **"Generated"** have corresponding meanings.

1.93. "Generic/Biosimilar Equivalent" means, with reference to a Licensed Product, and on a Licensed Product-by-Licensed Product and country-by-country basis, any product (including a "generic product," "biogeneric," "follow-on biologic," "follow-on biological product," "follow-on protein product," "follow-on gene therapy product", "similar biological medicinal product," or "biosimilar product") approved by way of an abbreviated regulatory mechanism by the relevant Regulatory Authority in a country in reference to such Licensed Product, that in each case: (a) is sold in the same country (or is commercially available in the same country) as such Licensed Product by any Third Party that is not a Sublicensee of Lilly or its Affiliates; and (b) either (i) contains an active substance that is highly similar to and has no clinically meaningful differences from the Licensed Product, or (ii) meets the equivalency determination by the applicable Regulatory Authority in such country (including a determination that the product is "comparable," "interchangeable," "bioequivalent," "biosimilar" or other term of similar meaning, with respect to the Licensed Product), in each case ((i) and (ii)), in a manner that permits substitution of such product for the Licensed Product under Applicable Law in such country.

1.94. “GLP Toxicology Study” means a toxicology study of a product in an animal species that is: (a) conducted in compliance with then-current GLP; and (b) designed to support the filing of an IND for such product.

1.95. “Good Clinical Practices” or “GCPs” means all applicable current Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable, (a) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (“ICH”) E6 and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50, 54, 56, 312 and 314, as may be amended from time to time, and (d) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity and confidentiality of trial subjects.

1.96. “Good Laboratory Practices” or “GLPs” means the applicable then-current standards for laboratory activities for pharmaceuticals, as set forth in the FDA’s Good Laboratory Practice regulations as defined in 21 C.F.R. Part 58, the Council Directive 87/18/EEC, as amended, the principles for Good Laboratory Practice and/or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development (“OECD”), and such standards of good laboratory practice as are required by the European Union and other organizations and governmental agencies in countries in which a Licensed Product is Researched and Developed, to the extent such standards are not less stringent than United States Good Laboratory Practice.

1.97. “Good Manufacturing Practices” or “GMPs” means the current Good Manufacturing Practices including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the WHO TRS 986 Annex 2,

TRS 961 Annex 6, TRS 957 Annex 2 and TRS 999 Annex 2, (d) ICH Q7 guidelines, and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.98. “Government Official” has the meaning set forth in Section 12.4.8.

1.99. "Governmental Authority" means any national, international, federal, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, and any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.100. "Gross Margin" means, with respect to a Co-Funded Product, the [**].

1.101. "Gross Margin Share" has the meaning set forth in [Section 10.5.3](#).

1.102. "HSR Act" has the meaning set forth in [Section 15.1](#).

1.103. "HSR Clearance Date" has the meaning set forth in [Section 15.1](#).

1.104. "Improvement" means any modification, enhancement, improvement or derivative.

1.105. "IND" means: (a) an investigational new drug application filed with the FDA for authorization to commence Clinical Trials and its equivalent in other countries or regulatory jurisdictions; and (b) all supplements and amendments that may be filed with respect to the foregoing.

1.106. "Indemnitee" has the meaning set forth in [Section 13.1.3](#).

1.107. "Indemnitor" has the meaning set forth in [Section 13.1.3](#).

1.108. "IND-Enabling Studies" means studies that are conducted to meet the requirements for filing an IND with a Regulatory Authority, including ADME (absorption, distribution, metabolism, and excretion) studies, GLP Toxicology Studies, pharmacology studies in animal models, studies required for the preparation of the CMC section of such IND, including studies relating to analytical methods and purity analysis, and formulation and Manufacturing development studies.

1.109. "Infringement" has the meaning set forth in [Section 11.9.1](#).

1.110. "Initial Target" means the lipoprotein(a) gene (LPA), Gene ID 4018.

1.111. "Initiation" means, [**].

1.112. "Intellectual Property Rights" means any and all proprietary rights provided under: (a) patent law, including any Patents; (b) trademark law; (c) copyright law; or (d) any other applicable statutory provision or common law principle, including trade secret law that may

provide a right in ideas, formulae, algorithms, concepts, inventions (whether or not patentable), or Know-How, or the expression or use thereof.

1.113. "Internal Compliance Codes" has the meaning set forth in Section 12.4.4.

1.114. "Internal Qualified Expenses" means any expenses incurred or accrued by a Party in the performance of activities related to the Research (in connection with performance of a Clinical Trial), Development (including activities related to efforts to submit Regulatory Filings) or Commercialization of a Licensed Product, with personnel costs charged on a FTE Rate basis unless otherwise mutually agreed by the Parties; provided, that: [**].

1.115. "IRA Impact" has the meaning set forth in Section 10.4.2(c).

1.116. "JCC" has the meaning set forth in Section 6.3.

1.117. "JDC" has the meaning set forth in Section 6.3.

1.118. "JFC" has the meaning set forth in Section 6.3.

1.119. "Joint IP" means: (a) all Know-How Generated jointly by or on behalf of Lilly (or its Affiliates or its or their Sublicensees) and Verve (or its Affiliates) solely in the course of activities conducted under this Agreement ("**Joint Know-How**"); and (b) any and all Patents that claim the Joint Know-How (collectively, "**Joint Patents**"); in each case excluding any Lilly IP Improvements and Verve IP Improvements. The existence of this Agreement (including the Parties' agreement to the Research and Development Plan(s) (and any revisions thereto), the fact that Verve's activities may be conducted under the Research and Development Plan, and payment for Verve's research and development activities thereunder), general discussions in any committee hereunder, or the disclosure or inclusion of an objective or problem to be solved will not be alone or in combination sufficient to render a Patent or Know-How Joint IP, unless those factors are relevant for inventorship under U.S. patent law.

1.120. "Joint Know-How" has the meaning set forth in Section 1.119.

1.121. "Joint Patents" has the meaning set forth in Section 1.119.

1.122. "JSC" has the meaning set forth in Section 7.1.

1.123. "JSC Subcommittee" has the meaning set forth in Section 7.2.

1.124. "Know-How" means any proprietary scientific or technical information, inventions, discoveries, results and data of any type whatsoever, in any tangible or intangible form,

including inventions, discoveries, databases, safety information, practices, methods, instructions, techniques, processes, drawings, documentation, specifications, formulations, formulae, knowledge, know-how, trade secrets, materials, skill, experience, test data and other information and technology applicable to formulations, compositions or products or to their manufacture, development, registration, use, marketing or sale or to methods of assaying or testing them, including pharmacological, pharmaceutical, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, physical and analytical, safety, quality control data, manufacturing, and stability data, studies and procedures, and manufacturing process and development information, results and data.

1.125. "Launch" means, with respect to a Co-Funded Product in any country in the Territory, the date of First Commercial Sale in such country. **"Launched"** when used as an

adjective shall have its correlative meaning.

1.126. "Licensed Know-How" means any Know-How Controlled by Verve or its Affiliates (including any Verve Gene Editor or Verve Delivery Element) as of the Effective Date or at any time during the Term that: (a) is Generated pursuant to a Research and Development Plan and specifically relates to a Licensed Target; or (b) is necessary or reasonably useful for the Exploitation of any Licensed Product, including components thereof (including in each case ((a) and (b)), Verve's interest in any Joint Know-How). Licensed Know-How as described in the foregoing subsection (b) includes any Know-How disclosed to Lilly by Verve prior to the Effective Date.

1.127. "Licensed Patents" means all Patents Controlled by Verve or its Affiliates as of the Effective Date or at any time during the Term that Cover Exploitation of any Licensed Product, including components thereof (including Verve's interest in any Joint Patents).

1.128. "Licensed Product" means any *in vivo* genome editing product that includes a Candidate. Co-Funded Products and Royalty Products shall each be considered Licensed Products. For clarity, [**] are and shall be treated as a single Licensed Product.

1.129. "Licensed Product Trademarks" has the meaning set forth in Section 11.14.

1.130. "Licensed Program" means a program to Generate, Research or Develop a Licensed Product Directed To a Licensed Target.

1.131. "Licensed Target" means, collectively, the Initial Target, the Additional Target (if selected by Lilly pursuant to Section 2.4), and the Replacement Target (if selected by Lilly pursuant to Section 2.5); in each case excluding any Terminated Target.

1.132. "Lilly Background IP" means any and all Patents and Know-How that Lilly or its Affiliates (a) Control as of the Effective Date, or (b) acquire Control of after the Effective Date outside the scope of the activities under this Agreement.

1.133. "Lilly Competitor" means a company that: (a) [**]; and (b) [**].

1.134. "Lilly Costs" has the meaning set forth in Section 10.5.2.

1.135. "Lilly Cost-Sharing COC Termination" has the meaning set forth in Section 6.6.

1.136. "Lilly Indemnatee" has the meaning set forth in Section 13.1.1.

1.137. "Lilly IP" means the Lilly Background IP, Lilly Sole IP and Lilly's interest in any Joint IP.

1.138. "Lilly IP Improvement" means: (a) any Know-How Generated by or on behalf of either Party (or its Affiliates or its or their Sublicensees) (or jointly) in the course of performing its activities under this Agreement that constitutes [**], in each case, solely to the extent that such Know-How (i) [**] and (ii) [**], and (iii) [**]; (b) any Know-How Generated by or on behalf of either Party (or its Affiliates or its or their Sublicensees) (or jointly) in the course of performing its activities under this Agreement that is [**]; and (c) any Patent that claims any of the foregoing Know-How.

1.139. "[]"** has the meaning set forth in Section [**].

1.140. "Lilly Patent" means any Patent claiming or constituting any Lilly IP.

1.141. "Lilly Sole IP" means (a) other than the [**], any Know-How Generated solely by or on behalf of Lilly (or its Affiliates or its or their Sublicensees) in the course of activities conducted under this Agreement, and any and all Patents that claim such Know-How, and (b) [**].

1.142. "Loss of Market Exclusivity" has the meaning set forth in Section 10.4.

1.143. "Losses" has the meaning set forth in Section 13.1.1.

1.144. "Manufacture" and "Manufacturing" means any and all activities related to the making, having made, production, manufacture, processing, filling, finishing, packaging, labeling, shipping, or holding of any product or any intermediate of any of the foregoing, including formulation, process development, process qualification and validation, scale-up, preclinical, clinical, and commercial manufacture and analytic development, product characterization, stability testing, quality assurance, and quality control.

1.145. “Manufacturing Technology Transfer” has the meaning set forth in Section 5.2.1.

1.146. “Material Amendment” means, with respect to a given Research and Development Plan (including the Research and Development Budget), an amendment thereto that would: (a) require Verve to expend resources beyond those agreed in the then-current Research and Development Plan (or, if silent as to resources to be expended, as otherwise estimated in good faith by Verve); *provided* that [**]; (b) modify the Research and Development Plan toward a performance metric other than Candidate Selection; or (c) modify the Candidate Selection Critical Success Factors.

1.147. “Materials Transfer Record Form” has the meaning set forth in Section 3.6.2.

1.148. “Milestone Events” has the meaning set forth in Section 10.3.

1.149. “Milestone Payments” has the meaning set forth in Section 10.3.

1.150. “Mix Patent” means any Licensed Patent that includes one or more claims that would, if segregated from the other claims in such Licensed Patent, be a Product Patent within the meaning of Section 1.169(b).

1.151. “Net Sales” means, with respect to a particular Licensed Product, the [**]:

[**];

Such amounts shall be determined from the books and records of Lilly or its Affiliate or Sublicensee, maintained in accordance with U.S. GAAP or, in the case of Sublicensees, such similar accounting principles, consistently applied. Lilly further agrees in determining such amounts, it will use Lilly’s then current standard procedures and methodology, including Lilly’s then current standard exchange rate methodology for the translation of foreign currency sales into U.S. Dollars or, in the case of Sublicensees, such similar methodology, consistently applied.

A qualifying amount may be deducted only once regardless of the number of the preceding categories that describes such amount. Sales between or among Lilly, its Affiliates and Sublicensees will be excluded from the computation of Net Sales if such sales are not intended for end use, but Net Sales will include the subsequent final sales to Third Parties by Lilly or any such Affiliates or Sublicensees.

In the event that the Licensed Product is sold in the form of a Combination Licensed Product (where **“Combination Licensed Product”** means any Licensed Product containing one or more other therapeutically active compound(s) or ingredients that is not a

Verve Gene Editor or Verve Delivery Element ("**Other Product**")), the Net Sales of the Licensed Product, for the purposes of determining royalty payments, shall be determined by [**].

In the event that the weighted average sale price of the [**] Product can be determined but the weighted average sale price of the Other Product cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by [**].

In the event that the weighted average sale price of the Other Product can be determined but the weighted average sale price of the [**] Product cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by [**].

In the event that the weighted average sale price of both the [**] Product and the Other Product in the Combination Licensed Product cannot be determined, the Net Sales of the Licensed Product shall be calculated by [**].

The weighted average sale price for a Licensed Product, other compound(s) or ingredients, or Combination Licensed Product shall be calculated [**] and such price shall be used during all applicable royalty reporting periods for the [**]. When determining the weighted average sale price of a Licensed Product, other compound(s) or ingredients, or Combination Licensed Product, the weighted average sale price shall be calculated by dividing the sales amount (translated into U.S. dollars) by the units of active ingredient sold during the [**] for the respective Licensed Product, other compound(s) or ingredients, or Combination Licensed Product. In the [**], a forecasted weighted average sale price will be used for the Licensed Product, other compound(s) or ingredients, or Combination Licensed Product. Any over or under payment due to a difference between forecasted and actual weighted average sale prices will be paid or credited in the first royalty payment of the [**].

1.152. "[] Agreement"** means the License Agreement by and between [**] and Verve, dated as of [**], as such agreement may be amended from time to time in accordance with its terms.

1.153. "Open Payments Law" has the meaning set forth in Section 12.4.6.

1.154. "Out-of-Pocket Costs" means the costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the Accounting Standards) incurred by a Party or any of its Affiliates in connection with the conduct of any applicable activities under this Agreement, excluding: (a) [**]; (b) [**]; and (c) [**].

1.155. "Party-Specific Regulations" has the meaning set forth in Section 12.4.3.

1.156. "Patents" mean: (a) patents and patent applications; (b) any and all divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates and the like of any such patents and patent applications; and (c) any and all foreign equivalents of the foregoing.

1.157. "Patent Working Group" has the meaning set forth in Section 11.8.4.

1.158. "Payor" has the meaning set forth in Section 10.9.

1.159. "Person" means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

1.160. "Personal Information" means, in addition to any definition for any similar term (e.g., "personal data" or "personally identifiable information" or "PII") provided by Applicable Laws, or by either Party in any of its own privacy policies, notices or contracts, all information that identifies, could be used to identify or is otherwise associated with an individual person, whether or not such information is directly associated with an identified individual person.

1.161. "Phase 1 Clinical Trial" means a clinical trial of a Licensed Product generally consistent with 21 C.F.R. § 312.21(a) (or the non-United States equivalent thereof).

1.162. "Phase 2 Assumption" means with respect to any Licensed Product, written notice delivered to Verve by Lilly within [**] following Completion of the last Phase 1 Clinical Trial with respect to the Licensed Product [**].

1.163. "Phase 2 Clinical Trial" means a clinical trial of a Licensed Product generally consistent with 21 C.F.R. § 312.21(b) (or the non-United States equivalent thereof).

1.164. "Phase 3 Clinical Trial" means a clinical trial of a Licensed Product generally consistent with 21 C.F.R. § 312.21(c) (or the non-United States equivalent thereof).

1.165. "PHSA" means the United States Public Health Service Act.

1.166. "Post-Marketing Activity Costs" means costs for activities relating to post-marketing [**].

1.167. "Pricing and Reimbursement Approval" means, with respect to a Licensed Product, the approval, agreement, determination or decision of any Regulatory Authority establishing the price or level of reimbursement for such Licensed Product, as required in a

given country or jurisdiction prior to sale of such Licensed Product in such country or jurisdiction.

1.168. “Product Failure” means, with respect to a Co-Funded Product, that Lilly has reasonably determined that continued Development of such Co-Funded Product or Commercialization thereof, for any indication or with any label, is not commercially reasonable (within the meaning of Commercially Reasonable Efforts, *mutatis mutandis*) due to one of the following: (a) [**]; (b) [**]; (c) [**]; (d) [**]; or (e) [**].

1.169. “Product Patent” means: (a) the [**] identified in Schedule 1.169, including (i) any and all divisionals, continuations, continuations-in-part, reissues, renewals, substitutions,

registrations, re-examinations, revalidations, extensions, supplementary protection certificates and the like of such Patent and (ii) any and all foreign equivalents of the foregoing; and (b) any Patent that solely and specifically claims the composition of matter of a Licensed Product, where the phrase “claims the composition of matter of a Licensed Product” requires that such Patent includes a claim that specifically includes a limitation that is Licensed Target specific (such as a gRNA of the applicable Licensed Product that has a spacer sequence that corresponds to or targets a protospacer sequence in the applicable Licensed Target).

1.170. “Program Results” has the meaning set forth in Section 14.1.1.

1.171. “Proof of Concept” means requirements set forth in a Research and Development Plan for achieving *in vitro* and *in vivo* proof of concept in a [**] (or as otherwise agreed upon by the Parties) for the relevant Licensed Target.

1.172. “Prosecute and Maintain” or “Prosecution and Maintenance” with respect to a particular Patent, means all activities associated with the preparation, filing, prosecution and maintenance of such Patent, together with the conduct of interferences, derivation proceedings, *inter partes* review and post-grant review, the defense of oppositions and other similar proceedings with respect to that Patent. “Prosecution and Maintenance” does not include infringement or enforcement actions or counterclaims or declaratory judgment actions for unpatentability, invalidity or unenforceability of such Patent that are brought by a Third Party in connection with an Infringement or enforcement action under Section 11.9.

1.173. “Receiving Party” has the meaning set forth in Section 14.1.2.

1.174. “Regulatory Approval” means, with respect to a country or other jurisdiction in the Territory, all approvals (including approvals of Regulatory Approval Applications, as well as any such accelerated approvals), licenses, registrations, or authorizations of any Regulatory

Authority necessary to initiate commercial distribution, marketing, and sale of a product in such country or other jurisdiction, including, as applicable, (a) BLA approval, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), (c) labeling approval, (d) Pricing and Reimbursement Approval, and (e) any of the foregoing approvals that are accelerated approvals, but excluding approval that is in the nature of emergency use authorization.

1.175. “Regulatory Approval Application” means a BLA or any similar or corresponding application outside of the United States in the Territory to obtain Regulatory Approval, including, with respect to the European Union, a marketing authorization application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition procedure or any other national approval.

1.176. “Regulatory Authority” means any applicable supra-national, federal, national, regional, state, provincial, or local regulatory agency, department, bureau, commission, council, Governmental Authority, or other government entity regulating or otherwise exercising authority with respect to the Exploitation of Licensed Products in the Territory (including any Governmental Authority whose approval is required for pricing or reimbursement by national health insurance or its local equivalent), including the FDA in the United States, the Medicines and Healthcare Products Regulatory Agency in the United Kingdom, and the EMA in the European Union.

1.177. “Regulatory Documentation” means all: (a) applications (including all INDs and Regulatory Approval Applications), registrations, licenses, authorizations, and approvals (including Regulatory Approvals); and (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents cited therein, including all adverse event files and complaint files; and (c) clinical and other data contained or relied upon in any of the foregoing, in each case ((a), (b) and (c)) to the extent specific to a Licensed Product.

1.178. “Regulatory Filings” means, collectively, any and all applications, filings, submissions, approvals (including supplements, amendments, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations, permits, notifications, and authorizations (including marketing and labeling authorizations), non-clinical and clinical study authorization applications or notifications (including all supporting files, writings, data, studies and reports) or waivers with respect to the testing or Exploitation of a Licensed Product made to

or received from any Regulatory Authority in a given country or jurisdiction, including INDs and BLAs.

1.179. "Replacement Target" means a **[**]** Option Target incorporated into the Research and Development Program pursuant to Section 2.5.

1.180. "Research" means any and all research, discovery, and non-clinical and preclinical activities up to (but not including) IND-Enabling Studies, including, as applicable: (a) **[**]**; and (b) **[**]**. Research may include Manufacturing solely to the extent necessary in support of the foregoing, but shall not include Development or Commercialization.

1.181. "Research and Development Budget" has the meaning set forth in Section 2.6.

1.182. "Research and Development Expenditures" has the meaning set forth in Section 3.4.

1.183. "Research and Development Milestone Event" has the meaning set forth in Section 10.3.1.

1.184. "Research and Development Milestone Payment" has the meaning set forth in Section 10.3.1.

1.185. "Research and Development Plan" has the meaning set forth in Section 2.6.

1.186. "Research and Development Program" has the meaning set forth in Section 2.1.

1.187. "Research and Development Program Records" has the meaning set forth in Section 3.6.1.

1.188. "Research Term" means:

(a) with respect to the Licensed Program for the Initial Target, the period ending on the fifth (5th) anniversary of the Effective Date, or, if earlier, upon fulfilment of those transfers set forth in Section 4.3 (Regulatory Filings; Regulatory Documentation and Program Results) and Section 5.2 (Manufacturing Technology Transfer) applicable following Completion of all Phase 1 Clinical Trials under such Licensed Program; and

(b) with respect to the Licensed Program for any Additional Target or Replacement Target, the period ending on the fifth (5th) anniversary of the commencement of the first activity undertaken pursuant to the Research and Development Plan associated with such Licensed Program, or, if earlier, upon fulfilment of those transfers set forth in Section 4.3

(Regulatory Filings; Regulatory Documentation and Program Results) and Section 5.2 (Manufacturing Technology Transfer) applicable following Completion of all Phase 1 Clinical Trials under such Licensed Program;

in each case ((a) and (b)), which period may be extended by Lilly pursuant to Section 2.3 or by mutual agreement of the Parties.

1.189. "Residuals" has the meaning set forth in Section 14.2.

1.190. "Restricted Person" has the meaning set forth in Section 12.4.9.

1.191. "Reversion Negotiation Period" has the meaning set forth in Section 16.6.3(a).

1.192. "Reversion Option" has the meaning set forth in Section 16.6.3(b).

1.193. "Royalty" or "Royalties" has the meaning set forth in Section 10.4.1.

1.194. "Royalty Product" means any Licensed Product, excluding any Co-Funded Product.

1.195. "Royalty Term" means, on a Licensed Product-by-Licensed Product and country-by-country basis, the period from First Commercial Sale until the latest to occur of: (a) expiration of the last Valid Claim included in a Licensed Patent that Covers such Licensed Product in such country; (b) expiration of all data, regulatory or market exclusivity periods (as may have been supplemented under Applicable Law) or supplemental protection certificates (other than Licensed Patents) covering the Licensed Product that provide exclusive marketing rights in such country; and (c) ten (10) years following the date of such First Commercial Sale of such Licensed Product in such country. For purposes of this definition, any Patent assigned to Lilly pursuant to Section 11.8.5 or 11.9.2 will be deemed to be a Licensed Patent.

1.196. "Sanctioned Territory" has the meaning set forth in Section 12.4.9(b).

1.197. "Settlement Sublicense Agreement" means an agreement pursuant to which (and to the extent that) Lilly or any of its Affiliates grants a sublicense of the rights granted under this Agreement to a Third Party solely for the purpose of settling or avoiding litigation or any *bona fide* intellectual property dispute related to: (a) the alleged infringement or misappropriation of any Patents or Know-How of a Third Party by a Licensed Product or the Exploitation thereof; or (b) the alleged non-infringement, invalidity or unenforceability of or challenge against any Patents Covering or claiming a Licensed Product.

1.198. "Skipped Milestone Event" has the meaning set forth in Section 10.3.3.

1.199. "Settlement Sublicensee" means a Third Party solely in its capacity as a sublicensee of the rights under this Agreement pursuant to a Settlement Sublicense Agreement.

1.200. "Sublicensee" means with respect to a given Party, any Third Party that is granted a sublicense of the rights granted under this Agreement by such Party or its Affiliate; but excluding any Settlement Sublicensee.

1.201. "Supply Price" means the price for the Manufacture of a Licensed Product as follows:

[**];

[**]. Notwithstanding anything to the contrary, the Supply Price will not include (x) [**] or (y) [**].

1.202. "Target" means a human gene.

1.203. "[]"** has the meaning set forth in Section [**].

1.204. "Technology Transfer Plan" has the meaning set forth in Section 5.2.

1.205. "Term" has the meaning set forth in Section 16.1.

1.206. "Terminated Product" means any product that was a Licensed Product but that was terminated in accordance with Section 16.2 or 16.3.

1.207. "Terminated Products or Targets" means, as the context requires, the applicable Terminated Product or Terminated Target.

1.208. "Terminated Target" means: (a) any Expired [**] Option Target, (b) any Target that was an Initial Target or Additional Target but that is replaced pursuant to Section 2.5; and (c) any Target that was terminated in accordance with Section 16.2 or 16.3.

1.209. "Territory" means worldwide.

1.210. "Third Party" means any Person other than Lilly or Verve or an Affiliate of Lilly or Verve.

1.211. "Third Party License Payments" has the meaning set forth in Section 10.4.2(a).

1.212. "Valid Claim" means, a claim of a Licensed Patent that: (a) either (i) [**], or (ii) [**]; and (b) is contained in (i) an issued, unexpired and granted Patent, which claim has not been

held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, (ii) a pending Patent, other than a Product Patent Prosecuted and Maintained by Lilly, that has not been expressly abandoned or finally rejected without the possibility of appeal or refiling, and which claim has been pending for no more than [**] from its earliest priority date in a national stage application, or (iii) a pending Product Patent Prosecuted and Maintained by Lilly that has not been expressly abandoned or finally rejected without the possibility of appeal or refiling.

1.213. "Verve Background IP" means any and all Patents and Know-How that Verve or its Affiliates (a) Control as of the Effective Date, or (b) acquire Control of after the Effective Date outside the scope of the activities under this Agreement.

1.214. "Verve Competitor" means (a) the companies listed on Schedule 1.214 or (b) a biotechnology or biopharmaceutical company with market capitalization of less than [**] Dollars (\$[**]) that is Developing or Commercializing a Competing Product.

1.215. "Verve Costs" has the meaning set forth in Section 10.5.1.

1.216. "Verve Delivery Element" means a molecule or group of molecules that, alone or in combination with other molecules, facilitate the delivery of a Verve Gene Editor to target cells and that is (a) Covered by Patents Controlled by Verve, or (b) developed using Know-How that is Controlled by Verve.

1.217. "Verve Gene Editor" means a molecule or group of molecules, other than a base editor, that effectuates (directly or indirectly), the deletion, insertion, modification, and/or replacement of DNA and that is (a) part of the Verve Platform, or otherwise is developed or derived from the Verve Platform, (b) Covered by Patents Controlled by Verve, or (c) developed using Know-How that is Controlled by Verve.

1.218. "Verve Genus Claim Patent" has the meaning set forth in Section 11.8.1(b).

1.219. "Verve Indemnitee" has the meaning set forth in Section 13.1.2.

1.220. "Verve IP" means the Verve Background IP, the Verve Sole IP, and Verve's interest in any Joint IP.

1.221. "Verve IP Improvement" means: (a) any Know-How Generated by or on behalf of either Party (or its Affiliates or its or their Sublicensees) (or jointly) in the course of performing its activities under this Agreement that constitutes [**], in each case, solely to the extent that such Know-How (i) [**]; and (ii) [**]; (b) any Know-How Generated by or on behalf of either Party

(or its Affiliates or its or their Sublicensees) (or jointly) in the course of performing its activities under this Agreement that is **[**]**; and (c) any Patent that claims any of the foregoing Know-How.

1.222. "Verve's Knowledge" means the actual knowledge of the individuals identified on Schedule 1.222 after due inquiry of their direct reports and other employees of Verve expected to have pertinent information with respect to the applicable matter.

1.223. "Verve Phase 1 Clinical Trial" means: (a) the first Phase 1 Clinical Trial for each Licensed Product; and (b) any other Phase 1 Clinical Trial that the Parties agree will be conducted by Verve pursuant to (and as set forth in) a Research and Development Plan.

1.224. "Verve Platform" means Verve's proprietary genome editing and delivery technology, in each case, relating to the discovery, characterization, selection, development, optimization and engineering of Verve Gene Editors and the delivery thereof with Verve Delivery Elements, including any modifications, derivatives or improvements thereto.

1.225. "Verve Sole IP" means (a) other than **[**]**, any Know-How Generated solely by or on behalf of Verve (or its Affiliates or its or their Sublicensees) in the course of activities conducted under this Agreement, and any and all Patents that claim such Know-How, and (b) **[**]**.

1.226. "[]"** has the meaning set forth in Schedule 1.226.

1.227. "[]"** has the meaning set forth in Schedule 1.227.

1.228. "Working Group" has the meaning set forth in Section 7.3.

ARTICLE 2

OVERVIEW; PROGRAMS AND RESEARCH AND DEVELOPMENT PLANS

2.1. Overview. The primary objective of Research and Development conducted under this Agreement is for the Parties to collaborate under Research and Development Plans, and thereafter in accordance with the terms of this Agreement, with the intended purpose of: (a) **[**]** focused on diseases implicated by the Licensed Target, and (b) Lilly further Developing such Licensed Products to ready them for Commercialization (collectively, the **"Research and Development Program"**).

2.2. Research and Development Program Structure. The Research and Development Program is divided into separate Licensed Programs, each governed by a comprehensive Research and Development Plan, each of which corresponds to a Licensed Target. Each

Research and Development Plan is agreed as of the Effective Date (in the case of the Initial Target) or created in accordance with Section 2.6.2.

2.3. Research Term; Extension. Each Research and Development Plan must be completed during the corresponding Research Term; provided that in no event will an expiration of the Research Term discontinue the Parties' Research and Development obligations with respect to a Licensed Program for which Initiation of a Phase 1 Clinical Trial has occurred and such Phase 1 Clinical Trial has not been Completed or terminated. On a Licensed Program-by-Licensed Program basis, Lilly may elect to extend the corresponding Research Term once for a period of up to twelve (12) months, upon notice delivered to Verve at least [**] prior to expiration of such Research Term. Lilly may not elect to extend the Research Term for a given Licensed Program more than once.

2.4. Additional Target. With notice delivered to Verve within [**] following achievement of Candidate Selection (pursuant to Section 3.2) under the Licensed Program Directed To the Initial Target (or, if such target was replaced in accordance with Section 2.5, the Replacement Target) (the "**Additional Target Election Period**"), and upon payment to Verve of a one-time, non-creditable and non-refundable payment of [**] Dollars (\$[**]) within [**] following provision by Lilly of such notice, Lilly shall have the right to select a [**] Option Target for incorporation into the Research and Development Program as an Additional Target, with such Additional Target being the subject of a new Licensed Program. To the extent that Lilly has not selected an Additional Target for incorporation into the Research and Development Program prior to the expiration of the Additional Target Election Period, then Lilly shall provide written notice to Verve on the date of such expiration of the Additional Target Election Period identifying which [**] Option Target shall continue to be reserved as a potential Replacement Target, and all rights and licenses hereunder to the [**] Option Target not so reserved by Lilly shall cease (an "**Expired [**] Option Target**"), and any Expired [**] Option Target shall no longer be eligible for incorporation under the Research and Development Program.

2.5. Replacement Target. While the Research Term is still active for a Licensed Program, if Lilly in good faith determines that (a) [**], or (b) [**], then Lilly shall have the right to replace the Initial Target or Additional Target (if applicable) with a different [**] Option Target,

which shall then be a "Replacement Target." Such Replacement Target will be the subject of a new Licensed Program under the Research and Development Program. All rights granted hereunder with respect to the replaced Target shall cease upon Lilly's election pursuant to this Section 2.5, all such rights thereto shall revert to Verve, and such replaced Target shall no longer be deemed a "Licensed Target." To the extent Lilly decides to exercise its rights to replace a

Target under this Section 2.5, Lilly shall notify Verve in writing of such decision, which notice shall include the basis for replacing such Target.

2.6. Research and Development Plans. Each Licensed Program will have a plan for the conduct of Research and Development through Completion of the first Phase 1 Clinical Trial for the applicable Licensed Product, with such plan satisfying the requirements of this Section 2.6 (each, a “**Research and Development Plan**”); provided, however, that the Parties may mutually agree to add additional activities to a Research and Development Plan (including further Phase 1 Clinical Trials). Each Party shall use Commercially Reasonable Efforts to perform those obligations assigned to it under each Research and Development Plan. Each Research and Development Plan shall include: (a) [**], (b) [**], (c) [**], (d) [**], (e) [**], (f) [**], and (g) [**].

2.6.1 The Research and Development Plan for the Licensed Program covering the Initial Target is attached hereto as Schedule 2.6.1.

2.6.2 The Research and Development Plan(s) for an Additional Target or Replacement Target shall be drafted by Verve promptly following receipt of notice under Section 2.4 or 2.5, and Verve shall thereafter: (a) provide a draft of such Research and Development Plan to the JSC within [**] of the requisite notice, and (b) finalize such Research and Development Plan and submit for JSC approval within the later of (x) [**] following the date on which Lilly names an Additional Target or Replacement Target or (y) [**] after Lilly submits comments on the initial draft of the Research and Development Plan. Each Research and Development Plan shall substantially follow, in form and substance, the form of the Research and Development Plan set forth on Schedule 2.6.1, except to the extent the Parties agree to any deviations from such form in relation to such Additional Target or Replacement Target.

2.6.3 Each Research and Development Plan will generally contain the following phases:

- (a) Stage 1: [**].
- (b) Stage 2: [**].
- (c) Stage 3: [**].

2.6.4 The JSC shall regularly review the Research and Development Plans (including, if applicable, the coordination of activities across Licensed Programs) and the progress of activities being conducted under the Research and Development Plans, in no event less frequently than [**]. Either Party may propose amendments to a Research and Development Plan (including the Research and Development Budget) from time to time as appropriate, to take into account completion, commencement, or cessation of activities contemplated in the

then-current Research and Development Plan for such Licensed Program or any newly available information related to such Licensed Program. Such amendments shall be effective upon JSC approval.

ARTICLE 3

RESEARCH AND DEVELOPMENT PROGRAM

3.1. Research and Development Program Responsibilities. All Research, Manufacturing and Development of Licensed Products through Completion of any Verve Phase 1 Clinical Trials, will be conducted in accordance with the Research and Development Plan for the relevant Licensed Program. Verve will be responsible for: (a) [**] Directed To Licensed Targets to support preclinical *in vivo* [**]; (b) [**]; (c) [**] for the Verve Phase 1 Clinical Trials; (d) [**]; and (e) any other activities assigned to Verve under a Research and Development Plan. Lilly will contribute [**]; and will be responsible for any Research or Development activities assigned to Lilly under a Research and Development Plan. The Parties shall cooperate in good faith with respect to, including through the sharing of Know-How in furtherance of, all preclinical Development activities with the guidance of the JSC. Without limiting the foregoing, all IND-Enabling Studies and Phase 1 Clinical Trials will be performed in material compliance with the Research and Development Plan and strict compliance with the Phase 1 Clinical Trial protocol as developed by Verve and approved by the JSC.

3.2. Candidate Selection. The JSC shall provide oversight for all preclinical Research and Development activities under each Research and Development Plan. [**]. Verve shall promptly notify the JSC of any determination by Verve that a Development Molecule has achieved the Candidate Selection Critical Success Factors, with the Candidate Selection Data Package accompanying such notification. [**]. In the event that the JSC determines such Development Molecule has achieved the Candidate Selection Critical Success Factors, it shall promptly notify the Parties of such determination ("**Candidate Selection**"), and such Development Molecule shall thereafter be considered a Candidate. [**]. Notwithstanding the foregoing, [**] in its sole discretion may elect to progress a Development Molecule despite a determination that the corresponding Candidate Selection Critical Success Factors have not been satisfied. [**].

3.3. Development Through Phase 1 Clinical Trials.

3.3.1 Verve Activities. Verve shall be responsible for preclinical Development and Regulatory Documentation relating to any Verve Phase 1 Clinical Trials for each Candidate under each Licensed Program. Verve shall develop a Phase 1 Clinical Trial protocol for each Verve Phase 1 Clinical Trial and submit such protocol for review and approval by the JSC. Verve shall

use Commercially Reasonable Efforts in the conduct of all Verve Phase 1 Clinical Trials, including by making updates to, and finalizing the investigator brochure, development safety update report and clinical study reports, and other Regulatory Documentation related thereto (subject to allocation of responsibilities as may be agreed upon by the Parties), provided that all such activities will be in material compliance with the corresponding Research and Development Plan and strict compliance with the Phase 1 Clinical Trial protocol as developed by Verve and approved by the JSC.

3.3.2CMC Requirements. Verve will develop appropriate CMC requirements for the Manufacture of Licensed Products (at Lilly's cost, as approved by the JSC) as needed to support Development. Notwithstanding the foregoing, Lilly shall have the right [**]. At least [**] prior to Initiation of any Verve Phase 1 Clinical Trial, Verve shall provide the JSC with a detailed final proposal for the parameters, specifications and requirements for such trial [**].

3.3.3Regulatory Submissions. At least [**] prior to any submission to a Regulatory Authority with respect to any Verve Phase 1 Clinical Trial, Verve shall provide the JSC with a draft of such submission, and Verve shall promptly consider and incorporate any reasonable feedback that is received by Verve within [**] after delivery of such draft. Verve will make available and promptly disclose to the JSC the results of any Verve Phase 1 Clinical Trial for each Licensed Product (including all Regulatory Documentation) and will keep such records (paper and electronic) as described herein. Verve will, until the longer of [**] after Lilly obtains Regulatory Approval of the first Licensed Product or as required by Applicable Law, maintain records of the results in sufficient detail and in good scientific manner appropriate for patent purposes, and in a manner that properly reflects all work done and results achieved in the performance of each Verve Phase 1 Clinical Trial for each Licensed Product (including all data in the form required to be maintained under any Applicable Law).

3.4.Licensed Program Funding.

3.4.1Verve Research Costs. Other than as set forth in Article 6, Lilly will fund (in accordance with Section 3.4.3) all Internal Qualified Expenses and Out-of-Pocket Costs incurred by Verve in its work under each Research and Development Plan (collectively, "**Research and Development Expenditures**"), as contemplated by the applicable Research and Development Budget. Other than as set forth in Article 6, Lilly shall bear its own Internal Qualified Expenses and Out-of-Pocket Costs with respect to any Research and Development that Lilly conducts under each Licensed Program. On at least [**] basis for each Licensed Program, no later than [**], the Parties shall discuss through the JSC the Research and Development Expenditures incurred during the prior [**] period ending [**], and the Research and Development

Expenditures expected to be incurred during the following [**]. Following such discussion, the JSC shall amend (if applicable) and approve the Research and Development Budget for the applicable Licensed Program for the following [**]. Notwithstanding the foregoing, Research and Development Expenditures incurred following the Cost-Sharing Option Effective Date to conduct a Phase 1 Clinical Trial associated with a Co-Funded Product shall not be subject to reimbursement by Lilly in accordance with this Section 3.4, and shall instead be reflected in the Expense and Margin Sharing and shared as between the Parties in accordance with Section 10.5.

3.4.2 Compliance with Research and Development Budget. Except as expressly set forth in this Section 3.4.2, Lilly shall in no event be responsible for Research and Development Expenditures incurred by Verve for activities allocated to Verve under a Research and Development Plan during any Calendar Year in excess of the applicable Research and Development Budget (or, such budgeted amount otherwise agreed upon in writing by the Parties) for such Calendar Year ("**Cost Overages**"), and such Cost Overages shall be the sole responsibility of Verve. [**]. Notwithstanding the foregoing, Lilly shall pay any Cost Overages set forth in a JSC-approved amendment to the Research and Development Budget or [**]. Following [**], the Parties shall discuss in good faith whether to amend the applicable Research and Development Budget and propose any amendment to the JSC; *provided* that [**].

3.4.3 Research and Development Expenditures; Reimbursement by Lilly. The Research and Development Expenditures shall be calculated and reimbursed in accordance with this Section 3.4.3 as follows:

(a) Lilly shall only be obligated to reimburse Verve to the extent that the nature and scope of the work performed by Verve [**] is set forth in the applicable Research and Development Plan, as amended from time to time by the Parties; [**];

(b) Verve shall invoice Lilly on a [**] basis for the amount of Internal Qualified Expenses and Out-of-Pocket Costs reflected in the Research and Development Budget for each Research and Development Plan (the "**Budgeted Research and Development Expenditures**"). Verve may issue such invoice on or after the [**] of the [**] to which the Budgeted Research and Development Expenditures relates, and Lilly will pay the Budgeted Research and Development Expenditures within [**] after receipt of such invoice. In association with delivery of such invoice, Verve shall also provide a report describing in reasonable detail the Internal Qualified Expenses and Out-of-Pocket Costs actually incurred by Verve while performing under the Research and Development Plan during the [**].

(c) The Parties will perform a reconciliation of Verve's actual Research and Development Expenditures as follows:

(i) Within [**] prior to the end of each [**], Verve will provide Lilly with an accounting of its actual Research and Development Expenditures for the [**] prior to such date along with any requisite documentation; *provided* that, Verve shall provide supporting documentation reasonably requested by Lilly.

(ii) If Lilly disputes (in good faith) any amounts detailed in the accounting, Lilly will notify Verve within [**] after receipt of the accounting, and the Parties will meet and attempt to resolve any such dispute. If the Parties are unable to resolve the dispute, Lilly shall have the right to have an independent, certified public accountant reasonably acceptable to Verve inspect Verve's records solely for the purposes of determining the accuracy of the reported Research and Development Expenditures in accordance with Section 10.12, applied *mutatis mutandis*. [**].

(iii) Within [**] after (A) the determination of the final accounting for such [**] period as set forth in Section 3.4.3(c)(ii) (if Lilly disputes the accounting) or (B) the expiration of the [**] period set forth in Section 3.4.3(c)(ii) for Lilly to dispute the accounting (if Lilly does not dispute the accounting), the Parties shall cause a true-up as follows: (X) if the actual Research and Development Expenditures for such [**] period exceed the Budgeted Research and Development Expenditures paid for such period, Lilly will pay Verve the difference (subject to Section 3.4.2); and (Y) if the Budgeted Research and Development Expenditures paid for such [**] period exceed the actual Research and Development Expenditures for such period, Verve will either (at Lilly's option) (i) provided that there are any then-current Research and Development Plans for which payment will be due in the amount of the difference or higher, issue a credit to Lilly in the amount of the difference to be used against future Budgeted Research and Development Expenditures payments, or (ii) pay Lilly the difference.

3.5.Subcontracting. Lilly and Verve may each engage its Affiliates or Third Party subcontractors (including contract research organizations and contract manufacturing organizations) to perform any portions of its rights or obligations hereunder; *provided* that [**], other than with respect to contractors (a) set forth on Schedule 3.5, engaged by Verve to conduct contract manufacturing; CMC; and contract research activities or (b) [**]. The activities of any such Third Party subcontractors will be considered activities of Lilly or Verve (as applicable) under this Agreement. Lilly and Verve (as applicable) shall ensure compliance by such Third Party subcontractors with the applicable terms of this Agreement. Each Party shall ensure, prior to engaging any Third Party subcontractor, that such Third Party subcontractor is subject to written agreements containing terms and conditions that enable such Party to comply with its obligations under this Agreement, including obligations of confidentiality on each such Third Party

subcontractor substantially similar to those under this Agreement and obligations consistent with the intellectual property provisions of Article 11. In no event will a Party have any payment obligations or liability directly to any subcontractor (without limiting Lilly's obligation to pay Research and Development Expenditures in accordance with Section 3.4).

3.6.Exchange of Materials; Research and Development Program Records; Reporting.

3.6.1In General. Each Party shall, and shall require its Affiliates and shall require its permitted Third Party subcontractors to, maintain complete, current, and accurate records of all work conducted and results achieved in the performance of the Research and Development Program (the "**Research and Development Program Records**") and all Know-How generated in conducting such activities. The Research and Development Program Records shall accurately reflect all such work done and results achieved in sufficient detail to verify compliance with applicable obligations under this Agreement and shall be in a good scientific manner appropriate for applicable patent and regulatory purposes.

3.6.2Transfer of Materials. Each Party may, to the extent provided under a Research and Development Plan or necessary to perform under a Licensed Program, transfer certain physical materials to the other Party that are not otherwise delivered under a supply or other separate agreement between the Parties or their Affiliates. In each such case, any materials provided to a Party shall (a) be accompanied by a mutually executed material transfer record substantially in the form of Schedule 3.6.2 (each a "**Materials Transfer Record Form**"), (b) only be used for the purposes set forth on the Materials Transfer Record Form executed for such materials, and (c) be subject to any other additional terms set forth on the Materials Transfer Record Form executed for such materials, the receiving Party's signature to any Materials Transfer Record Form shall constitute its binding agreement to (i) only use the applicable materials for such limited use(s), and (ii) comply with any such additional terms with respect to the applicable materials. The receiving Party shall not transfer such materials to any Third Party, except as necessary to exercise its rights or perform its obligations under this Agreement, and any such Third Party recipient of the materials shall be obligated to terms no less protective of the Party providing such materials as those set forth herein.

3.6.3Audits. Lilly shall have the right, during normal business hours and upon reasonable notice but not more frequently than [**], using an independent Third Party selected by Lilly and reasonably acceptable to Verve (and subject to the entry into a customary confidentiality agreement with Verve), to inspect [**], solely to the extent necessary to confirm Verve's compliance with (a) [**], and (b) [**]. Upon completion of any such audit, the Third Party will share such Third Party's conclusions but not any of Verve's actual books and records with Lilly and Verve simultaneously. Any such conclusions are provided for compliance purposes only. Verve agrees to promptly seek remediation of any noncompliance issues identified. Lilly

and its representatives shall maintain all information disclosed to it as Verve's Confidential Proprietary Information in accordance with Article 14.

3.6.4 Information Sharing with Lilly; Adverse Event Reporting.

(a) Verve shall on a regular basis during the Research Term (with frequency as mutually agreed between the Parties) share with Lilly data Generated by Verve during the Research Term (i) regarding Verve Gene Editors or Verve Delivery Elements that, at such time, are incorporated within any Development Molecules, Candidates or Licensed Products, and (ii) is

necessary for Lilly's Exploitation of Licensed Products; *provided*, that if such data is Generated pursuant to an agreement with a Third Party, then the foregoing disclosure requirement is subject to Verve's confidentiality obligations therein. In addition, to the extent that Lilly requests information from Verve before Regulatory Approval of a Licensed Product (or any time during the Term in order to comply with the request of a Regulatory Authority or to comply with Applicable Law) that it reasonably believes is useful with respect to the Development of such Licensed Product, Verve will use good faith efforts to provide the requested information to Lilly provided that the requested information is not subject to Verve's obligations to a Third Party.

(b) Verve shall on a regular basis during the Term (during the Research Term and thereafter), with frequency as mutually agreed between the Parties, share with Lilly any material adverse safety finding with respect to any Verve Gene Editors or Verve Delivery Elements that, to Verve's Knowledge, is reasonably expected to have an adverse impact on any Licensed Product.

3.7. Certain Standards Applicable to Work.

3.7.1 To the extent applicable and in compliance with Applicable Laws, all Research conducted by either Party will be conducted in accordance with Lilly's "Eli Lilly and Company Good Research Practices" and "Eli Lilly and Company Animal Care and Use Requirements for Animal Researchers and Suppliers". In addition, the Parties each agree to comply with all Applicable Laws in the performance of this Agreement, including any Applicable Laws regarding data privacy and data security, including implementing technical and organizational measures to protect all information under this Agreement that are appropriate and that provide no less protection than both (i) good industry practice (i.e., in accordance with ISO 27001 and/or similar industry standards) and (ii) its measures to protect its own information of a similar nature or importance. For the purposes of this Agreement "**Eli Lilly and Company Good Research Practices**" means the compiled set of shared research quality standards defining how the research laboratories of Eli Lilly and Company conduct good science for non-regulatory work as set forth in Schedule 3.7.1(i). For purposes of this Agreement, "**Eli Lilly and Company Animal**

Care and Use Requirements for Animal Researchers and Suppliers” means the guidelines relating to animal care and use for research done on behalf of Eli Lilly and Company as set forth in Schedule 3.7.1(ii). If Lilly reasonably requests, Verve will complete a self-assessment examination form based on such quality standards. If Lilly has not done so prior to the Effective Date, a duly authorized representative of Lilly may make [**] to Verve after the Effective Date at a mutually agreed time during Verve’s regular business hours for the purpose of conducting a quality assessment or quality audit for non-regulated work, which shall be performed at Lilly’s cost and expense.

3.7.2 To the extent permitted by Verve’s agreements with such Third Party subcontractors, Lilly may conduct compliance audits of Verve’s or Verve’s Affiliates’ Third Party subcontractors, similar in scope to the audits under Section 3.6.3, engaged in work related to this Agreement, during normal business hours at a mutually agreed time, no more than [**], except in the case of audits for cause to ensure compliance with applicable GCP, GLP, and GMP requirements, *provided* that Lilly has requested such audit with written notice of at least [**] or as otherwise required under the operative Third Party agreement and such audit does not unreasonably interfere with the audited entity’s operations. All such audits shall be done at Lilly’s cost and expense. [**]. To the extent Verve’s agreement with any Third Party subcontractor does not permit audits in accordance with this Section 3.7.2, then (a) [**], or (b) [**]. Verve shall use Commercially Reasonable Efforts to [**].

3.8. Additional Candidates. At any time after Candidate Selection, the Parties may, by mutual agreement in writing, replace a Candidate or add a Candidate to a Licensed Program. In such event: (a) the Parties will amend the applicable Research and Development Plan (and Research and Development Budget) to account for Research and Development of a new Development Molecule, and, if mutually agreed, to extend or renew the Research Term; (b) Lilly shall fund Research and Development Expenditures with respect to such new Candidate; and (c) Verve shall have the right to exercise the Cost-Sharing Option to the same extent as if there had been no prior Candidate (or, with respect to an added Candidate, an existing Candidate) under the applicable Licensed Program, *provided* that, if Verve has previously paid the Cost-Sharing Fee with respect to a prior replaced Candidate, then no further Cost-Sharing Fee would be due for the replacement Candidate.

ARTICLE 4

LATER DEVELOPMENT AND COMMERCIALIZATION

4.1. Later Development. Other than as set forth in Sections 3.1 and 3.3, Lilly shall be responsible for the Development (including Research conducted pursuant to Clinical Trials) of

Licensed Products (including any Phase 2 Clinical Trial readiness activities for each Licensed Product after Phase 1 Clinical Trials as set forth in the applicable Research and Development Plan) and leading and controlling all such Clinical Trials; *provided*, that Verve shall cooperate with Lilly in such Development (or, as applicable, Research) activities as reasonably requested by Lilly and at Lilly's expense. Subject to the terms of this Agreement, as between the Parties, Lilly shall have sole discretion and authority with respect to all decisions concerning the Development (including Research conducted pursuant to Clinical Trials) of Licensed Products after conduct of the last Phase 1 Clinical Trial therefor, including the clinical and regulatory strategy of Licensed Products covered under this Agreement. Verve shall not conduct any Research or Development activities with respect to any Licensed Product other than as set forth in the Research and Development Plan without Lilly's prior written consent and approval.

4.2.Regulatory Obligations; Commercialization. No later than [**] after Completion of the first Phase 1 Clinical Trial with respect to a Licensed Product, Lilly shall deliver written notice to Verve that either (a) Lilly will continue Development of such Licensed Product and, in such case, whether any additional Phase 1 Clinical Trials will be conducted before a Phase 2 Clinical Trial (upon delivery of such notice, with respect to such Licensed Product, "**Development Advancement**") or (b) Lilly is terminating this Agreement with respect to such Licensed Product under Section 16.3.1. The Research and Development Plan and Research and Development Budget shall be amended to the extent necessary to account for any additional Phase 1 Clinical Trials that Lilly and Verve have mutually agreed that Verve will perform after Development Advancement. Lilly shall be responsible for Commercialization of the Licensed Products in the Field in the Territory and, following Development Advancement with respect to a Licensed Product, Lilly shall (a) use Commercially Reasonable Efforts to Develop and secure Regulatory Approval for such Licensed Product and (b) Commercialize such Licensed Product in at least [**]. Subject to the foregoing and the other terms of this Agreement, all decisions concerning Exploitation of the Licensed Products, including the clinical and regulatory strategy of the foregoing, the Manufacturing, marketing and sale of the foregoing, and the design, price and promotion of the foregoing, are within the sole discretion of Lilly.

4.3.Regulatory Matters.

4.3.1Regulatory Filings Ownership. All Regulatory Filings for Clinical Trials performed by Verve related to Licensed Products (including all ownership and rights thereto) will be filed in the name of Verve; *provided*, that, after Development Advancement (or, if later, Completion of the last Verve Phase 1 Clinical Trial for the applicable Licensed Product), Verve and Lilly shall cooperate to transfer such Regulatory Filings to Lilly as promptly as reasonably practicable, but in no event shall such transfer occur later than [**] following Development

Advancement (or, if later, Completion of the last Verve Phase 1 Clinical Trial for the applicable Licensed Product). [**]. Following Development Advancement, all Regulatory Filings and Regulatory Approvals for Clinical Trials performed by Lilly relating to such Licensed Product will be filed in the name of Lilly, and Lilly will own all right, title and interest in and to any and all Regulatory Filings and Regulatory Approvals for such Licensed Product. In connection with the foregoing, Verve shall execute all documents and take all actions, including any additional filings with the relevant Regulatory Authorities, as are necessary or otherwise reasonably requested by Lilly to vest all ownership and rights to the Regulatory Filings and Regulatory Approvals with Lilly and to reflect Lilly as the holder of all Regulatory Filings and Regulatory Approvals. Lilly may reference other regulatory approvals and related regulatory filings of Verve (or its Affiliates) to the extent related to the Licensed Products.

4.3.2Regulatory Responsibilities. Except as may be provided in the Research and Development Plan, following Development Advancement, as between the Parties, Lilly shall be responsible for the preparation, submission, and maintenance of all Regulatory Filings and obtaining Regulatory Approvals with respect to such Licensed Product and shall have sole control over all interactions with the applicable Regulatory Authority (including written communications and meetings with Regulatory Authorities, safety management, and adverse event reporting to the appropriate Governmental Authorities concerning Licensed Products). Lilly will use Commercially Reasonable Efforts to provide Verve the right to have an appropriate representative attend any meetings with Regulatory Authorities addressing [**]. Verve shall reasonably cooperate with Lilly, at Lilly's reasonable request, with respect to any regulatory matters related to Licensed Products. Verve shall notify Lilly in writing within [**] (or as promptly as reasonably possible) of any unannounced inspections by any Regulatory Authority, or notification of an announced regulatory inspection with respect to any Verve Phase 1 Clinical Trial. Verve may reference, access and use (with a right to grant further rights of reference, access and use) any data, information or results generated in the course of the Development (or, if applicable, Research conducted pursuant to a Clinical Trial) of any Licensed Product or contained or referenced in any Regulatory Filings transferred to Lilly hereunder; *provided* that such access and use shall be subject to the rights and licenses granted to Lilly pursuant to this Agreement.

4.3.3Licensed Know-How. In the event any Regulatory Authority requires disclosure of Licensed Know-How in connection with a Licensed Product, Verve shall, and shall cause its Affiliates to, reasonably cooperate with Lilly, its Affiliates or their Sublicensees to address such requirement and shall take such actions as are reasonably necessary to comply with or otherwise satisfy the requirements of such Regulatory Authority with respect to the Licensed Know-How, subject to confidentiality obligations, if available.

4.4.Information Sharing with Verve; Adverse Event Reporting.After Phase 2 Assumption and for the remainder of the Term (with frequency as mutually agreed between the Parties), Lilly shall share with Verve any (i) material adverse safety finding with respect to any Licensed Product, (ii) any data that it Generates relating to Licensed Products, Verve Gene Editors or Verve Delivery Elements that evidences a significant negative effect on safety that is specifically related to the mechanism of the Verve Gene Editor or Verve Delivery Element of a

Licensed Product and (iii) any top line clinical data relating to the efficacy or potency of Licensed Products, Verve Gene Editors or Verve Delivery Elements.

ARTICLE 5

MANUFACTURING

5.1.Manufacture of Licensed Products.

5.1.1Pre-Clinical Development and Phase 1. Verve shall be responsible for the Manufacture of Licensed Products to support Research and Development through Completion of all Verve Phase 1 Clinical Trials for each Licensed Program, with such Manufacturing conducted in accordance with the applicable Research and Development Plan. [**]. Verve may elect to engage a CMO to Manufacture the Licensed Products in support of Research and Development through Completion of all Verve Phase 1 Clinical Trials; provided that either (a) [**] or (b) [**] (i) [**] and (ii) [**], for satisfaction of GCP, GLP or GMP requirements. [**].

5.1.2Post-Phase 1. Other than as set forth in Section 5.1.1, Lilly shall be solely responsible for and have the exclusive right to Manufacture all Licensed Products at its sole cost and expense, including as required to support Development (or, if applicable, Research conducted pursuant to a Clinical Trial) and Commercialization thereof.

5.2.Technology Transfer.

5.2.1With respect to each Licensed Product for which Lilly has determined to commence a Phase 2 Clinical Trial, as requested by Lilly and at Lilly's expense, Verve shall cooperate with Lilly to conduct a manufacturing technology transfer sufficient to enable Lilly (or its designated CMO) to Manufacture (or have Manufactured by such CMO) such Licensed Product (a "**Manufacturing Technology Transfer**") for Development and Commercialization, with such transfer occurring pursuant to an agreed upon Technology Transfer Plan.

5.2.2In connection with each Manufacturing Technology Transfer following the applicable request by Lilly pursuant to Section 5.2.1, the Parties shall promptly agree to a

technology transfer plan addressing necessary access to Verve personnel and facilities, as well as suitable protections for Verve's confidential manufacturing processes and other trade secrets (the "**Technology Transfer Plan**"). Any such technology transfers, and compliance with the Technology Transfer Plan, shall be overseen by a Working Group of the JSC established for such purposes. Lilly will pay any Internal Qualified Expenses and Out-of-Pocket Costs reasonably incurred by Verve in its work to prepare and perform work under each Technology Transfer Plan in accordance with Section 3.4.2, *mutatis mutandis*.

ARTICLE 6

COST-SHARING OPTION; CO-FUNDED PRODUCTS

6.1. Grant and Exercise of Cost-Sharing Option. Lilly hereby grants Verve an option to elect to participate in Expense and Margin Sharing with respect to each Licensed Product, exercised only in accordance with this Article 6 (such option, the "**Cost-Sharing Option**"). Within **[**]** following Completion of the last Phase 1 Clinical Trial for a Licensed Product, Lilly shall provide Verve with a Phase 2 Assumption notice as well as a copy of its existing (as of such date)

plans for the Development and Commercialization of such Licensed Product (along with any existing budgets associated therewith) that (a) **[**]**, and (b) **[**]** (collectively, the "**Cost-Sharing Option Information Package**"). Each Party acknowledges that the Cost-Sharing Option Information Package shall be prepared in good faith but is non-binding, provided for informational purposes only, and inherently employs placeholder assumptions as necessary to generate appropriate estimates. Verve may exercise the Cost-Sharing Option by written notice to Lilly given within **[**]** following Lilly's delivery of the Cost-Sharing Option Information Package (such period, the "**Cost-Sharing Election Period**"). During the Cost-Sharing Election Period, Lilly shall promptly respond to reasonable requests from Verve regarding the Cost-Sharing Option Package, and make reasonably available those representatives that Lilly anticipates will perform or directly oversee the activities contemplated with respect to such Licensed Product, in each case, to answer any reasonable questions Verve may have (provided that, Lilly shall in no event be required to provide information or documentation not in existence as of Completion of the last Phase 1 Clinical Trial for a Licensed Product). The Cost-Sharing Option shall expire if not exercised by Verve on or prior to the last day of the Cost-Sharing Election Period.

6.2. Cost-Sharing Option Requirements Assessment. If Verve timely exercises the Cost-Sharing Option during the Cost-Sharing Election Period, then, within **[**]** after such exercise, Verve's **[**]** and an executive designated by Lilly shall meet and discuss Verve's assessment that it has achieved the Cost-Sharing Requirements; provided that if another Licensed Product is already a Co-Funded Product under this Agreement, Lilly may elect to forego such discussion of

Verve's Cost-Sharing Requirements pursuant to this Section 6.2 by notice to Verve in writing within such [**] period. Within [**] after such meeting, Lilly shall notify Verve in writing as to whether it agrees that the Cost-Sharing Requirements are satisfied. If Lilly disputes that the Cost-Sharing Requirements are satisfied after any such discussion, the dispute will be resolved in accordance with the dispute resolution process in Section 17.2 and Section 17.3. If it is determined through such dispute resolution process that the Cost-Sharing Requirements are not satisfied, Verve will be deemed not to have exercised the Cost-Sharing Option and the Cost-Sharing Option Effective Date will be deemed not to have occurred.

6.3. Commencement of Expense and Margin Sharing. Effective upon the Cost-Sharing Option Effective Date: (a) the Licensed Product shall automatically be deemed a Co-Funded Product for all purposes under this Agreement, (b) Verve shall participate in the Expense and Margin Sharing with respect to such Co-Funded Product as further described herein, and (c) the JSC shall form (with respect to the first exercised Cost-Sharing Option) and delineate responsibilities for (in addition to those set forth herein) a joint development committee (the "**JDC**"), joint commercialization committee (the "**JCC**"), and a joint finance committee (the "**JFC**"); provided that such committees shall not receive any decision-making authority. If any dispute regarding Cost-Sharing Requirements is proceeding in accordance with Section 6.2, then Verve's participation in the Expense and Margin Sharing with respect to such Co-Funded Product will be tolled until the resolution of such proceeding. Promptly after resolution of such proceeding resulting in a decision that Verve satisfies the Cost-Sharing Requirements, the Parties shall provide to each other the reports set forth in Section 10.5 for the period from the Cost-Sharing Option Effective Date through the date of resolution of such proceeding. Within [**] after Lilly delivers to Verve a report of the Co-Funded Product Sharing Amounts incurred by the Parties during such period in accordance with Section 10.5.5(c), Verve shall pay to Lilly Verve's share of such Co-Funded Product Sharing Amounts in accordance with Section 10.5.5.

6.4. Cost-Sharing Fee. Within [**] following the Cost-Sharing Option Effective Date for a Co-Funded Product, Verve shall pay Lilly a one-time, non-refundable (other than in

accordance with Section 6.5), non-creditable payment equal to [**] Dollars (\$[**]) (the "**Cost-Sharing Fee**"). If any dispute regarding Cost-Sharing Requirements is proceeding in accordance with Section 6.2, then Verve's obligation to pay the Cost-Sharing Fee will be tolled until [**] after the resolution of such proceeding. Within [**] after any resolution of such a proceeding resulting in a decision that Verve satisfies the Cost-Sharing Requirements, Verve shall pay to Lilly the Cost-Sharing Fee.

6.5. Cost Sharing Budget; Progress. During a Cost-Sharing Term, Lilly shall, through the JDC or JCC (*as applicable*), provide: (a) a [**] update as to progress made with respect to the

Development and Commercialization of such Co-Funded Product, with such update being delivered in a manner determined by the applicable committee; and (b) on or prior to [**] (the “**Budget Date**”) of [**], a good faith budget of the estimated Lilly Costs for the [**] following such date and a good faith, high level estimated budget for the [**] following such date. The Parties acknowledge that the foregoing budgets are provided for informational purposes only, with placeholder assumptions as necessary to generate appropriate estimates.

6.6.Verve Change of Control. If Verve undergoes a Change of Control and, as of the closing date of such Change of Control, such Acquirer is engaged in a Competing Program with respect to a Co-Funded Product, then Lilly may elect to terminate the Cost-Sharing Term with respect to the applicable Co-Funded Product by notifying Verve within [**] of Lilly’s receipt of a Change of Control notification in accordance with Section 18.8.1 (a “**Lilly Cost-Sharing COC Termination**”), with such termination being effective as of the [**] in which such notice is delivered by Lilly. Following the effective date of a Lilly Cost-Sharing COC Termination, (a) the corresponding Co-Funded Product shall constitute a Royalty Product for all purposes under this Agreement, (b) Expense and Margin Sharing shall no longer apply for such Royalty Product, (c) obligations of the JDC, JCC and JFC with respect to such Royalty Product shall cease, and (d) within [**] after such Lilly Cost-Sharing COC Termination, Lilly shall pay Verve an amount equal to (i) the Cost-Sharing Fee, plus (ii) [**] percent ([**]%) of the Eligible Costs incurred by Verve with respect to such Royalty Product prior to the Lilly Cost-Sharing COC Termination, minus (iii) any Gross Margin received by Verve prior to the Lilly Cost-Sharing COC Termination. In the event that Lilly elects not to exercise a Lilly Cost-Sharing COC Termination with respect to a Co-Funded Product, then any obligation for Lilly to provide Verve, the JSC or a subcommittee thereof with updates, reports, summaries or the like with respect to such Co-Funded Product shall cease effective upon closing of such Change of Control, except for those obligations set forth in Section 10.5.

6.7.Cost-Sharing Opt-Out. Verve may terminate the Cost-Sharing Term with respect to any Co-Funded Product by providing written notice to Lilly within [**] after the Budget Date, which termination will be effective on [**] following the applicable Budget Date (e.g., if Verve’s termination notice is provided on [**], then the Cost-Sharing Term will end on [**]). Following the effective date of such termination: (a) the corresponding Co-Funded Product shall thereafter constitute a Royalty Product for all purposes under this Agreement; (b) Expense and Margin Sharing shall no longer apply for such Royalty Product; and (c) obligations of the JDC, JCC and JFC with respect to such Royalty Product shall cease, and such committees will immediately be disbanded if there are no other Co-Funded Products at such time.

6.8.Co-Funded Product Divestment. At any time after [**], Lilly may elect (in its sole discretion) to sell (or, otherwise convey) to a Third Party all or substantially all of the Lilly-

controlled assets primarily relating to such Co-Funded Product so as to divest to such Third Party any future Development and Commercialization for such Co-Funded Product (a **“Co-Funded**

Product Divestment”). In such event, Lilly shall notify Verve promptly (but, in no event later than [**]) following any such election. Lilly shall be solely responsible for conducting the Co-Funded Product Divestment process, and Verve shall cooperate with any reasonable request from Lilly with respect to the conduct of such process or as is otherwise required to facilitate such Co-Funded Product Divestment. In furtherance of, and in connection with, any Co-Funded Product Divestment, Lilly shall be permitted to sublicense to such Third Party (in accordance with the terms of this Agreement) any rights granted by Verve hereunder. Lilly shall use reasonable efforts to ensure that Lilly’s agreement with such Third Party governing such Co-Funded Product Divestment includes provisions (as applicable) (a) requiring reporting of Net Sales to Verve consistent with the reporting requirements set forth under this Agreement and (b) permitting Verve to audit such reports (or, permit Lilly to audit such reports) in a manner consistent with this Agreement. [**]. As of the closing date of the Co-Funded Product Divestment (the **“Co-Funded Product Divestment Effective Date”**), the Cost-Sharing Term with respect to such Co-Funded Product shall terminate, and such Co-Funded Product will thereafter be deemed a Royalty Product except that the following payment obligations will apply in lieu of any milestones or royalty obligations under Sections 10.3 or 10.4: (x) within [**] following a Co-Funded Product Divestment Effective Date, Lilly shall pay Verve [**].

6.9.Lilly Cost-Sharing Termination. Lilly may terminate the Cost-Sharing Term with respect to any Co-Funded Product by providing written notice to Verve at any time after [**]. In such event, for a period of [**] after delivery of such notice (the **“Cost-Sharing Wind-Down Period”**), the Expense and Margin Sharing shall be adjusted, effective upon the beginning of the first [**] wholly within the Cost-Sharing Wind-Down Period, such that (y) Lilly shall be entitled to and responsible for (as applicable) [**] percent ([**]%) of the Development Costs, Eligible Costs, and Gross Margin Share during the Cost-Sharing Wind-Down Period, and (z) Verve shall be entitled to and responsible for (as applicable) [**] percent ([**]%) of the Development Costs, Eligible Costs and Gross Margin Share during the Cost-Sharing Wind-Down Period. The Cost-Sharing Term with respect to the applicable Co-Funded Product shall terminate effective upon the expiration of the Cost-Sharing Wind-Down Period. Following the effective date of such termination: (a) the corresponding Co-Funded Product shall thereafter constitute a Royalty Product for all purposes under this Agreement; (b) Expense and Margin Sharing shall no longer apply for such Royalty Product; and (c) obligations of the JDC, JCC and JFC with respect to such Royalty Product shall cease, and such committees will immediately be disbanded if there are no other Co-Funded Products at such time.

ARTICLE 7

GOVERNANCE

7.1. Joint Steering Committee. Within [**] after the Effective Date, the Parties shall establish a cross-functional, joint steering committee (the “**JSC**”) composed of up to [**] representatives from each Party (*provided* that each Party has an equal number of representatives) that will oversee and provide strategic guidance with respect to the research and sharing contemplated under Article 2 and Article 3, and have the functions and powers further set forth in Section 7.5. Each Party shall appoint its respective representatives to the JSC from time to time, and may change its representatives, in its sole discretion, effective upon reasonable prior written notice to the other Party designating such change. The representatives from each Party on the JSC shall have appropriate technical credentials, experience and knowledge pertaining to and ongoing familiarity with gene editing products and the collaboration of the Parties under this Agreement.

Lilly's Alliance Manager shall be responsible (in consultation with Verve's Alliance Manager) for circulating agendas no later than [**] prior to each JSC meeting and distributing minutes of the JSC meetings. The JSC shall meet [**] (or at such greater frequency as the JSC members may agree) for so long as it remains in effect. The JSC may conduct such meetings by telephone, videoconference, or in person. Each Party may call special meetings with at least [**] prior written notice, or a shorter time period in exigent circumstances, to resolve particular matters requested by such Party that are within the purview of the JSC. Meetings are effective only if at least [**] of the JSC for each Party participates in such meeting. Each Alliance Manager shall be permitted to attend meetings of the JSC as a non-voting observer. Each Party may invite a reasonable number of other participants, in addition to its representatives, to attend JSC meetings in a non-voting capacity; *provided*, that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party. Such Party shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement. Each Party is responsible for its own expenses incurred in connection with participating in and attending all such meetings.

7.2. JSC Subcommittees. The JSC may, from time to time, establish subcommittees as it deems necessary to further the purposes of this Agreement and Research and Development Program (a “**JSC Subcommittee**”), including as necessary to oversee and coordinate the Parties' activities related to the Research and Development Program, and may delegate activities to such JSC Subcommittees. Each JSC Subcommittee shall undertake the activities delegated to it by the JSC. During the process of establishing each JSC Subcommittee, the JSC shall agree regarding

which matters within the scope of the JSC's authority that each such JSC Subcommittee may resolve on its own (with discretion to refer any matter to the JSC for a final decision) and which matters such JSC Subcommittee will advise the JSC regarding (and with respect to which such advice-specific matters the JSC must resolve). Each Party may replace any of its designated JSC Subcommittee representatives at any time with reasonable prior written notice to the other Party. Each Party shall designate one (1) of its representatives on each JSC Subcommittee to serve as the co-chairperson of such committee, who will be jointly responsible for calling meetings of the JSC Subcommittee, circulating agendas and performing administrative tasks required to assure efficient operation of the JSC Subcommittee, but shall not have any extra or additional votes or authority. The co-chairpersons or their designees shall alternate responsibility for circulating agendas no later than [**] prior to each meeting of the applicable JSC Subcommittee and distributing minutes of meetings of the applicable JSC Subcommittee.

7.3.Working Groups. The JSC may establish working groups consisting of members from both Verve and Lilly (each, a "**Working Group**"), with each such Working Group to be responsible for carrying out certain aspects of the activities of the Research and Development Program or each individual Research and Development Plan as specified by the JSC when establishing such Working Group. From time to time, the Parties may establish additional Working Groups as needed to oversee particular activities and/or projects. Each Working Group shall undertake the activities delegated to it by the JSC. The Working Groups will serve in an advisory role to the JSC or a JSC Subcommittee, but will not have any independent decision-making authority over any matter.

7.4.Alliance Managers. Within [**] after the Effective Date, each Party shall appoint one (1) individual to act as the alliance manager for such Party (each, an "**Alliance Manager**"). Without limiting the responsibilities and authorities of the JSC (as expressly set forth herein), the Alliance Managers shall each be the primary point of contact for the Parties regarding performance of the Research and Development Plan and shall help facilitate all such activities thereunder. Either

Party, upon prior written notice to the other Party, may change its Alliance Manager. For clarity, the same employee may not be both the Alliance Manager and a representative appointed by a Party to the JSC. In conducting themselves on the JSC or any subcommittee, all representatives of both Parties shall consider diligently, reasonably and in good faith all input received from the other Party. The Lilly Alliance Manager will be responsible for performing administrative tasks required to assure efficient operation of the JSC.

7.5.Functions and Powers of the JSC. Except where expressly provided to the contrary hereunder, the JSC shall be responsible for overseeing, coordinating and approving all

development activities and strategies relating to the Research and Development Program. Notwithstanding anything to the contrary herein, all responsibilities and decision-making authority of the JSC, the JSC Subcommittees and the Working Groups shall be subject to the terms of this Agreement, including this Section 7.5, and in particular the JSC shall:

7.5.1oversee the collaborative activities of the Parties under this Agreement;

7.5.2establish JSC Subcommittees (which themselves may establish Working Groups) as necessary to coordinate and conduct the activities of the Parties hereunder, and terminate or discontinue JSC Subcommittees, as necessary;

7.5.3receive and discuss reports from JSC Subcommittees as may be established by the JSC from time to time, and provide guidance thereto;

7.5.4direct and oversee the JSC Subcommittees as may be established by the JSC from time to time on all significant strategic issues that fall within the purview of such subcommittees;

7.5.5review, discuss and approve the Research and Development Plan for each Additional Target and each Replacement Target;

7.5.6review, discuss and approve any amendments to the Research and Development Plans that may be necessary or desired;

7.5.7review progress of activities against any budgets established for the same;

7.5.8at least [**] review progress under each Research and Development Plan and adopt any amendments to each Research and Development Plan (including the Research and Development Budget);

7.5.9resolve disputes escalated from a JSC Subcommittee that could not be resolved by the members of such JSC Subcommittee;

7.5.10review a comparison of actual Research and Development Expenditures versus Research and Development Budget year to date and review and approve changes to the Research and Development Budget;

7.5.11facilitate the exchange of Know-How or any materials required hereunder;

7.5.12review, discuss and approve a publication plan that will govern any

publication activities (excluding patent publications) with respect to Licensed Programs;

7.5.13 coordinate and lead any necessary unwinding or transition activities of the Parties in the event a given Research and Development Plan is terminated;

7.5.14 provide a forum in which the Parties may discuss matters related to the Development and proposed Commercialization of Co-Funded Products;

7.5.15 review, discuss and approve the Phase 1 Clinical Trial protocol developed by Verve and any amendments thereto; and

7.5.16 perform such other duties and tasks as are expressly assigned to the JSC or JSC Subcommittee under this Agreement.

7.6. Decisions; Limitations.

7.6.1 Each JSC member will take into reasonable consideration the recommendations and concerns of the other members and make its decisions in good faith using reasonable business judgment. The JSC and any JSC Subcommittees will use reasonable efforts to make decisions on all matters within the scope of its authority by consensus, with representatives of each Party having, collectively, one (1) vote on behalf of that Party. If the JSC cannot reach consensus or a dispute arises that cannot be resolved within the JSC, the dispute will be escalated to the Executive Officers of each Party. If the Executive Officers are unable to resolve the dispute within [**] following reference of the dispute to them, then final decision making may be exercised as follows: (a) [**] would have the right to make final decisions with respect to [**], and (b) [**] would have the right to make final decisions with respect to [**]. Notwithstanding the foregoing, [**] will not be within the scope of either Party's final decision making authority and will require mutual agreement of the Parties. The Party with final decision making authority (x) will take into reasonable consideration the recommendations and concerns raised by the other Party, (y) will make such decisions in good faith using reasonable business judgment, which will not be unreasonably delayed, and (z) will not exercise its final decision-making authority in a manner that would require the other Party to perform any act that the other Party reasonably believes would violate Applicable Law or any Third Party contractual obligations of such Party.

7.6.2 Notwithstanding anything to the contrary set forth in this Agreement, the JSC will not have the right to: (a) amend, modify or waive compliance with any term or condition of this Agreement; (b) make any decision that is expressly stated in this Agreement to require the mutual agreement of the Parties; or (c) resolve any claim or dispute regarding the interpretation of this Agreement, including whether or in what amount a payment is owed under this

Agreement, whether a Party is in breach of this Agreement or whether any Milestone or success metric has been achieved.

7.7.JSC Discontinuation. Unless otherwise agreed to by the Parties, the JSC will automatically disband with immediate effect at the later of (a) the end of the last Verve Phase 1 Clinical Trial for a Licensed Product; or (b) the time during which Verve no longer has any active role in Development of a Licensed Product. Notwithstanding the foregoing, the JSC will be reinstated upon exercise by Verve of the Cost-Sharing Option for the purposes set forth in Section 6.3.

ARTICLE 8

LICENSE RIGHTS

8.1.Exclusive License Grants to Lilly. Verve (on behalf of itself and its Affiliates) hereby grants to Lilly an exclusive (even as to Verve and its Affiliates), royalty-bearing (excluding Co-Funded Products as set forth in Section 6.3), license, with the right to grant sublicenses (through multiple tiers, as provided in Section 8.6) under the Licensed Know-How and Licensed Patents solely to Exploit Licensed Products in the Field in the Territory.

8.2.Non-Exclusive License Grants to Lilly. Verve hereby grants to Lilly a non-exclusive, royalty-free, perpetual irrevocable, fully-paid license, with the right to grant sublicenses without restriction, under the Verve Sole IP assigned by Lilly to Verve pursuant to Section 11.1.1, *provided* that (a) [**], and (b) [**].

8.3.[].**

8.4.Non-Exclusive License Grant to Verve. Lilly hereby grants to Verve:

8.4.1a non-exclusive, royalty-free license, without the right to grant sublicenses (except to Verve's Affiliates or Third Party subcontractors to perform any part of Verve's rights or obligations hereunder in accordance with Section 3.5), under the Lilly Background IP, solely as and to the extent necessary or useful for Verve to perform its obligations under this Agreement, including its Research, Development and Manufacturing activities under a Research and Development Plan; and

8.4.2a non-exclusive, royalty-free, perpetual irrevocable, fully-paid license, with the right to grant sublicenses without restriction, under the Lilly Sole IP assigned by Verve to Lilly pursuant to Section 11.1.2, *provided* that (a) [**], and (b) [**].

8.5.[].** The licenses granted by Verve to Lilly include [**]; provided that Lilly will have [**]: (a) [**]; or (b) [**].

8.6.Sublicenses. Lilly may grant one or more sublicenses under the rights and licenses granted to it under Article 8, in full or in part, to Lilly's Affiliates and to Third Parties (in each case, with the right to sublicense through multiple tiers); provided that: (a) prior to the end of the Cost-Sharing Election Period, Lilly may not grant a sublicense of the rights in Section 8.1 to a Third Party (excluding any sublicense granted to a Third Party contractor performing activities in furtherance of Development of the Product on behalf of Lilly or its Affiliates) in [**]; (b) any such permitted sublicense is consistent with and subject to the terms and conditions of this Agreement; and (c) Lilly shall remain responsible for the performance of Lilly's obligations under this Agreement and shall be responsible for all actions of each such Sublicensee as if such Sublicensee were the Party hereunder. Any sublicense to a Third Party Sublicensee must be set forth in a written sublicense agreement that includes provisions that require such Sublicensee to comply with all the obligations, restrictions, terms and conditions of this Agreement that are applicable to the rights being granted to such Sublicensee and that enable Lilly to comply with its obligations under this Agreement. Notwithstanding any sublicense, Lilly will remain responsible for each Affiliate's and Sublicensee's compliance with the applicable terms of this Agreement as if such activities were conducted by Lilly and for any payments due hereunder with respect to any activities of any Sublicensee. Within [**] after execution of any sublicense agreement with a Third Party pursuant

to which Lilly or any of its Affiliates grants exclusive rights to Develop or Commercialize a Licensed Product for use in [**], or any material amendment thereof, Lilly shall provide Verve with a copy of such sublicense agreement or amendment (as applicable) (provided that Lilly may redact any terms of such sublicense agreement or amendment to the extent not relevant to either Party's rights or obligations under this Agreement or verification of its compliance with the requirements of this Agreement).

8.7.No Implied Rights. Except as expressly set forth in this Agreement, neither Party shall be granted by implication or otherwise, any license or right to or under any other Intellectual Property Right, including any trademarks, Know-How, or Patents, of the other Party.

8.8.Safe Harbor Research. Neither Party, by entering into this Agreement, is forfeiting any rights that such Party may have to perform research activities in compliance with 35 U.S.C. § 271(e)(1) or any experimental or research use exemption that may apply under Applicable Law or in any country.

8.9.[] Agreement.**

8.9.1 Lilly acknowledges and agrees that the rights, licenses and sublicenses granted by Verve to Lilly under this Agreement to the extent constituting [**] are subject to the terms of the [**] Agreement. Without limiting Lilly's obligations under Section 11.7.1, Verve hereby acknowledges and agrees that Verve is and shall be responsible for all payments or consideration of any kind or nature owed to [**]. In no event will Lilly be obligated to make payments to Verve (other than pursuant to Section 11.7.1) or any other Person in consideration for Intellectual Property subject to the [**] Agreement. At Verve's request, Lilly shall use Commercially Reasonable Efforts to, and cause its Affiliates and all Sublicensees to use Commercially Reasonable Efforts to, take such reasonable actions, as may be required to assist Verve in complying with its obligations under the [**] Agreement, solely to the extent applicable to Lilly's rights or obligations under this Agreement. Without limiting any of the foregoing, Lilly agrees to be bound by the terms and conditions of Sections [**] of the [**] Agreement, as applicable with respect to sublicenses granted by Verve to Lilly in this Agreement under the [**] Agreement.

8.9.2 No later than [**] after the Effective Date, the Parties shall [**], (ii) [**], (iii) [**]; provided that Verve shall be permitted to [**], (iv) [**]; provided that Verve shall be permitted to [**], (v) [**] and (vi) [**].

8.10.[] Agreement.** Notwithstanding anything to the contrary in this Agreement, the Patents and Know-How licensed under the [**] Agreement shall not constitute Licensed Patents and Licensed Know-How unless and until the Parties agree on a separate sublicense agreement (or an amendment to this Agreement) to include such Patents and Know-How in the Licensed Patents and Licensed Know-How. [**].

ARTICLE 9

EXCLUSIVITY

9.1.Verve Exclusivity Obligations. During the Term, neither Verve nor any Affiliate that Verve controls (within the meaning set forth in Section 1.7, a "**Verve Controlled Affiliate**") shall (by themselves, or with or through any Third Party), directly or indirectly, (a) conduct or

participate in a Competing Program or (b) grant any Intellectual Property Rights, including by assignment of or granting of a license or covenant not to sue under any Intellectual Property Rights, that [**].

9.2.Transactions Involving Competing Programs. If, (a) after the Effective Date, any Third Party becomes a Verve Controlled Affiliate as a result of a merger, acquisition,

consolidation, assets sale, or other similar transaction (whether in a single transaction or series of related transactions, and including a Change of Control) (each, an **“Acquired Verve-Controlled Affiliate”**), and, as of the closing date of such transaction, such Acquired Verve-Controlled Affiliate is engaged in activities, the continuation of which would violate Section 9.1, then (b) [**].

9.3.Exception. The Parties acknowledge that [**].

ARTICLE 10

FEES, ROYALTIES, & PAYMENTS

10.1.Upfront Payment. As partial consideration for the rights granted by Verve to Lilly pursuant to the terms of this Agreement, Lilly shall pay Verve a one-time, non-refundable non-creditable payment equal to Thirty Million Dollars (\$30,000,000) within ten (10) Business Days following the Effective Date.

10.2.Investment. As of the Execution Date, Lilly and Verve entered into the Stock Purchase Agreement, whereby Lilly agreed to purchase Thirty Million Dollars (\$30,000,000) of Verve stock.

10.3.Milestone Events and Payments. Lilly shall make the non-refundable and non-creditable payments to Verve described in this Section 10.3 (collectively, the **“Milestone Payments”**) after the achievement of the corresponding events set forth in this Section 10.3 with respect to Royalty Products (collectively, the **“Milestone Events”**).

10.3.1Research and Development Milestones. Lilly shall pay Verve the below Milestone Payments (each, a **“Research and Development Milestone Payment”**) within [**] after, on a Royalty Product-by-Royalty Product basis, the Milestone Event is first achieved by Verve, Lilly, or their respective Affiliates or Sublicensees (as applicable) with respect to a Royalty Product (or Research and Development thereof) (each, a **“Research and Development Milestone Event”**). Each Research and Development Milestone Payment shall be payable only once per Royalty Product. For clarity, Co-Funded Products are not Royalty Products and accordingly no Research and Development Milestone Payment shall be payable on achievements of Co-Funded Product(s) if the Research and Development Milestone Event occurs during the Cost-Sharing Term. If Lilly discontinues development of a Royalty Product and a later Royalty Product Directed To the same Licensed Target later achieves a Research and Development Milestone Event previously achieved by the discontinued Royalty Product, the corresponding Research and Development Milestone Payment will not be due for the replacement Royalty Product. Lilly may deduct from any Research and Development Milestone Event [**] percent ([**]%) of the Existing

License Share payable with respect to milestone payments for Royalty Products (it being understood that for each dollar so deducted, Lilly will bear a dollar of cost and will not be entitled to offset that dollar against other milestones or royalties).

Table 10.3.1 – Research and Development Milestone Payments

| | Milestone Event | Milestone Payment |
|------|-----------------|-------------------|
| (1) | [**] | [**] |
| (2) | [**] | [**] |
| (3) | [**] | [**] |
| (4) | [**] | [**] |
| (5) | [**] | [**] |
| (6) | [**] | [**] |
| (7A) | [**] | [**] |
| (7B) | [**] | [**] |

10.3.2Commercial Milestones. Lilly shall pay to Verve the below Milestone Payments (each, a “**Commercial Milestone Payment**”) within [**]following the end of the [**] in which, on a Royalty Product-by-Royalty Product basis, the Milestone Event is first achieved for such Royalty Product (each, a “**Commercial Milestone Event**”). Each Commercial Milestone Payment shall be payable only once per Royalty Product. Lilly may deduct from any Commercial Milestone Payment [**] percent of the Existing License share payable with respect to milestone payments for Royalty Products (it being understood that for each dollar so deducted, Lilly will bear a dollar of cost and will not be entitled to offset that dollar against other milestones or royalties); provided, for clarity, in the event amounts eligible for deduction against a Commercial Milestone Payment are not applied because such amounts exceeded such Commercial Milestone Payment, those amounts may instead be deducted against a subsequent Commercial Milestone Payment or any subsequent Royalties due pursuant to Section 10.4.

Table 10.3.2 – Commercial Milestone Payments

| | Milestone Event | Milestone Payment |
|-----|---|-------------------|
| (1) | Calendar Year Net Sales Exceed USD \$[**] | USD \$[**] |
| (2) | Calendar Year Net Sales Exceed USD \$[**] | USD \$[**] |
| (3) | Calendar Year Net Sales Exceed USD \$[**] | USD \$[**] |

| | Milestone Event | Milestone Payment |
|-----|---|-------------------|
| (4) | Calendar Year Net Sales Exceed USD \$[**] | USD \$[**] |

10.3.3 *Limitations; Skipped Milestone Events.* If any Milestone Event (each, a “**Skipped Milestone Event**”) has not been achieved at the time of achievement of a Milestone Event having a higher number in the applicable table than such Skipped Milestone Event, then each such Skipped Milestone Event shall be deemed achieved at the time of achievement of the higher number Milestone Event, except that no “[**]” milestone will be deemed to achieve any other “[**]” milestone.

10.4. Royalties.

10.4.1 *Royalty Rates.* Subject to this Section 10.4, during the Royalty Term, Lilly shall pay Verve, on a Royalty Product-by-Royalty Product and country-by-country basis, the royalty payments on Net Sales in each Calendar Year of each Royalty Product in the Territory at the below rates (the “**Royalty**” or “**Royalties**”). Such rates are intended to be tiered and incremental, and the higher incremental rate will only apply to that portion of the annual Net Sales of the applicable Royalty Product that falls within the indicated range of Net Sales. All Royalties payable pursuant to this Section 10.4.1 are subject to reduction as further described in Section 10.4.2.

Table 10.4.1 – Royalty Rates

| Net Sales in a Calendar Year | Royalty Rate |
|---|--------------|
| Net Sales in a Calendar Year less than [**] Dollars (USD \$[**]) | [**]% |

| | |
|---|-------|
| Net Sales in a Calendar Year greater than or equal to [**] Dollars (USD \$[**]) but less than [**] Dollars (USD \$[**]) | [**]% |
| Net Sales in a Calendar Year greater than or equal to [**] Dollars (USD \$[**]) | [**]% |

10.4.2 **Royalty Reductions.**

(a) **Third Party Payments.** On a Royalty Product-by-Royalty Product and country-by-country basis, Lilly may deduct from any Royalty payment owed to Verve for the sale of a given Royalty Product in a given country an amount equal to [**] percent ([**]%) (or such other amount set forth in Section 11.7.2(c)(i) or (ii), as applicable) of (i) any payments made by Lilly to a Third Party or Acquirer of Verve in consideration for a right or license under such

Person's interest in Patents or Know-How reasonably necessary or reasonably useful for Exploitation of such Royalty Product (including the components therein) for a reasonable portion of such payments solely attributable to such Royalty Product, and (ii) any share of [**] as provided in Section 11.7 (collectively, "**Third Party License Payments**"). In no event will Royalties payable to Verve for each Royalty Product be reduced in a Calendar Quarter, solely as a result of this Section 10.4.2(a), by more than [**] percent ([**]%) *provided* that (y) an amount eligible for deduction in a given Calendar Quarter which was not applied because it would have resulted in a reduction of Royalties paid in such Calendar Quarter by more than [**] percent ([**]%) can be applied instead in any subsequent Calendar Quarter during the Royalty Term, and (z) deductions taken against a Milestone Payment or Royalty payment pursuant to Section 10.3 for a [**] shall not be counted towards the [**] percent ([**]%) cap in eligible Third Party License Payment deductions set forth in this Section 10.4.2(a). As between Verve and a Third Party against whom Lilly may make the same deduction as is permitted under this Section 10.4.2(a), pro-rata allocation of such deduction shall be calculated in a manner consistent with Lilly's internal practices using a weighted average based on Lilly's total payable royalty burden for such Royalty Product. For the purposes of clarity, payments made by Lilly as described under (i) or (ii) above that are made to an Acquirer of Verve shall be considered Third Party License Payments hereunder (subject to a reduction in the event that Lilly takes the licenses pursuant to Section 11.7.2(c)(i) or (ii), as applicable, as a result of Verve not taking such license).

(b) *Loss of Market Exclusivity.* On a country-by-country basis, from and after (and including) the Calendar Quarter within which the first commercial sale of the first Generic/Biosimilar Equivalent occurred with respect to a Royalty Product ("**Loss of Market Exclusivity**"), the Royalty with respect to such Royalty Product in such country shall be permanently reduced as follows: (i) to **[**]** percent (**[**]**%) of the rates provided in Section 10.4.1 when, for **[**]** consecutive Calendar Quarters, the Net Sales of the applicable Royalty Product in the applicable country are **[**]** percent (**[**]**%) or less than those Net Sales recorded by Lilly for such Royalty Product in such country in the Calendar Quarter immediately preceding Loss of Market Exclusivity, and (ii) to **[**]** percent (**[**]**%) of the rates provided in Section 10.4.1 when, for **[**]** consecutive Calendar Quarters, the Net Sales of the applicable Royalty Product in the applicable country are **[**]** percent (**[**]**%) or less than those Net Sales recorded by Lilly for such Royalty Product in such country in the Calendar Quarter immediately preceding Loss of Market Exclusivity.

(c) *Inflation Reduction Act.* If, on a Royalty Product-by-Royalty Product basis, there is application of a maximum fair price under the Inflation Reduction Act in the U.S. with respect to a Royalty Product (an "**IRA Impact**") **[**]**.

(d) *Valid Claim.* In any Calendar Quarter during the Royalty Term, for a Royalty Product for which there is no Valid Claim that Covers such Royalty Product in a country, the Royalty for such Royalty Product will be reduced in such country by **[**]** percent (**[**]**%) for such Calendar Quarter and thereafter for the remainder of the Royalty Term unless and until a Valid Claim issues. Notwithstanding the foregoing, issuance of a Valid Claim that Covers such Royalty Product following expiration of the Royalty Term for a Royalty Product in a country shall not operate to reinstate such Royalty Term, and such Royalty Term shall continue to be expired.

(e) *Cumulative Royalty Reductions and Limitations.* Each of the potential Royalty reductions in this Section 10.4.2 may be taken in addition to, and not in lieu of, any other potential reductions set forth in this Section 10.4.2; *provided* that in no event will the cumulative effect of the reductions under Sections 10.4.2(a), 10.4.2(b)(i), 10.4.2(c) and 10.4.2(d) result in a reduction

of Royalty rates specified in Section 10.4.1 by more than **[**]** percent (**[**]**%) of the amount that would have been due in the absence of any such reductions.

10.4.3 Payment; Reports. Royalty payments due by Lilly to Verve will be calculated and reported for each Calendar Quarter from and after the Calendar Quarter in which Net Sales are first made hereunder. All Royalties due shall be paid within **[**]** after the end of each Calendar Quarter and shall be accompanied by a written report setting forth, with respect to each

Calendar Quarter, on a Royalty Product-by-Royalty Product and country-by-country basis: (a) Net Sales of the Royalty Product by Lilly and its Affiliates and Sublicensees in such country, and (b) a calculation of Royalties (including detail on any applicable offsets) due on such Net Sales. For the avoidance of doubt, nothing in this Agreement will require Lilly to disclose its (or any of its Affiliates' or Sublicensees') [**].

10.4.4 *Records*. Lilly shall keep, and shall cause its Affiliates and Sublicensees to keep, complete and accurate records which may be necessary to ascertain properly and to verify the royalty payments due hereunder. Such records shall be kept for such period of time required by Applicable Laws, but no less than [**] following the end of the [**] to which they pertain.

10.5. Calculation and Payment of Expense and Margin Sharing. With respect to each Co-Funded Product during the Cost-Sharing Term, the Parties will share Development Costs and Gross Margin (minus Eligible Costs), (such share, the “**Expense and Margin Sharing**”), as further set forth below, as follows:

10.5.1 *Verve Cost Reporting*. No later than [**] after the end of each Calendar Quarter including and following the Cost-Sharing Option Effective Date, Verve will provide Lilly a detailed, itemized report for the Development Costs (if any and as applicable) and Eligible Costs incurred by Verve or its Affiliates in such Calendar Quarter, as applicable, for the Co-Funded Products (collectively, “**Verve Costs**”), such report to be in the form set forth in Schedule 10.5.1 or in such other form as the Parties may mutually agree from time-to-time.

10.5.2 *Lilly Cost Reporting*. No later than [**] after the end of each Calendar Quarter including and following the Cost-Sharing Option Effective Date, Lilly will provide Verve a detailed, itemized report of the Development Costs and Eligible Costs, excluding [**], incurred by Lilly or its Affiliates in such Calendar Quarter (or, with respect to the first Calendar Quarter of the Cost-Sharing Term, any Eligible Costs or Development Costs incurred prior to the Cost-Sharing Option Effective Date that qualify for Expense and Margin Sharing pursuant to this Agreement), as applicable, for the Co-Funded Products (collectively, the “**Lilly Costs**”), such report to be in the form set forth in Schedule 10.5.1 or in such other form as the Parties may mutually agree from time-to-time. Under no circumstances will Lilly be obligated to disclose [**].

10.5.3 *Gross Margin Share Reporting*. No later than [**] after the end of each Calendar Quarter beginning in the Calendar Quarter in which a Co-Funded Product is first Launched, Lilly will provide Verve with a report setting out the Gross Margin minus Eligible Costs (the “**Gross Margin Share**”), excluding [**], calculated by Lilly in respect of such Co-Funded Product for such Calendar Quarter for all sales of such Co-Funded Product. For the avoidance of doubt, nothing in this Agreement will require Lilly to disclose its (or any of its Affiliates' or Sublicensees') [**].

10.5.4Income Taxes. Subject to Section 10.8, income and withholding taxes imposed on either of the Parties hereunder will not be included in cost sharing hereunder.

10.5.5Allocation, Reconciliation and True-Up.

(a) *Allocation of Development Costs and Eligible Costs.* On a Calendar Quarter-by-Calendar Quarter basis, in respect to each Co-Funded Product, (a) Lilly shall be responsible for sixty percent (60%) of the Development Costs and Eligible Costs during the Cost-Sharing Term, and (b) Verve shall be responsible for forty percent (40%) of the Development Costs and Eligible Costs during the Cost-Sharing Term.

(b) *Allocation of Gross Margin Share.* On a Calendar Quarter-by-Calendar Quarter basis, in respect to each Co-Funded Product, (a) Lilly shall be entitled to or responsible for sixty percent (60%) of the Gross Margin Share during the Cost-Sharing Term, and (b) Verve shall be entitled to or responsible for forty percent (40%) of the Gross Margin Share during the Cost-Sharing Term.

(c) *True-Up.* Within [**] after the end of each [**], Lilly will provide Verve a report of the amount each Party is responsible for under Section 10.5.5(a) for such Calendar Quarter, and a report of the amount each Party is entitled to receive under Section 10.5.5(b), as Lilly calculates such amounts based on reports provided under Sections 10.5.1 and 10.5.2, and the report provided by Lilly under Section 10.5.3 (the net of such amounts, the “**Co-Funded Product Sharing Amounts**”). The Parties will make a balancing payment between the Parties in order to effect the sharing of the Co-Funded Product Sharing Amounts within [**] after delivery of such report of the Co-Funded Product Sharing Amount.

10.6.Late Payments. If any payment properly due under this Agreement and not subject to a good faith dispute is not paid when due in accordance with the applicable provisions of this Agreement, the payment shall accrue interest at the rate equal to [**] or the maximum rate allowable by Applicable Law, whichever is less. The payment of such interest shall not limit the Party entitled to receive payment from exercising any other rights it may have as a consequence of the lateness of any payment.

10.7.Settlement Sublicense Agreements. Any payments received by Lilly under a Settlement Sublicense Agreement [**].

10.8.Taxes on Income. Each Party shall pay all taxes (including related interest and penalties) imposed on its share of income arising directly or indirectly from the efforts of, or the receipt or deemed receipt of any payment by, such Party under this Agreement.

10.9.Tax Withholding. If any taxes (including related interest and penalties) are required to be withheld by a Party with respect to an amount payable to the other Party under this Agreement, such Party shall: (a) withhold such taxes from the payment made to the other Party; (b) timely pay the withheld taxes to the proper taxing authority; (c) send proof of payment to the other Party; and (d) reasonably assist the other Party in its efforts to obtain a refund of or credit for such tax payment. Any amount actually withheld and remitted by a Party to a taxing authority pursuant to this Section 10.9 shall be treated for all purposes of this Agreement as paid to the other Party. No amount shall be withheld, or a reduced amount shall be withheld, as applicable, if a Party that is entitled to a payment, [**] prior to the date such payment is due, furnishes the other Party with the necessary tax forms and other documents required by Applicable Law, which shall be in a form reasonably satisfactory to the Party receiving the documents, identifying that the relevant payment is exempt from tax or subject to a reduced tax rate. [**].

10.10.Tax Cooperation. The Parties agree to use reasonable efforts to cooperate with each other with respect to taxes, including by completing and filing documents required or permitted under the provisions of any Applicable Laws in connection with a claim of exemption from, or entitlement to a reduced rate of, withholding taxes in respect of any Payment or in connection with any claim to a refund of or credit for any payment of taxes in respect of any Payment. Notwithstanding the foregoing, for clarity, it is the receiving Party's sole responsibility to prepare and provide required documents necessary to claim an exemption from withholding tax or to claim a reduced rate of withholding tax, at recipient's sole expense. Any information shared pursuant to this Section 10.10 in respect of tax matters shall constitute Confidential Proprietary Information and be subject to the provisions of Article 14 (provided that each Party shall have the right to disclose such Confidential Proprietary Information to any tax authority to comply with a request or requirement of such tax authority or a requirement under Applicable Law).

10.11.Financial Records. Each Party shall, and shall cause its Affiliates and its and their Sublicensees to, keep complete and accurate financial books and records which may be necessary to ascertain properly and to verify the payments due hereunder. Each Party shall, and shall cause its Affiliates and its and their Sublicensees to, retain such books and records until the later of: (a) [**] after the end of the period to which such books and records pertain; and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof) or for such longer period as may be required by Applicable Law.

10.12.Audits.

10.12.1 During the Term, upon the written request of the other Party, each Party shall, and shall cause its Affiliates and its and their Sublicensees to, permit a “Big Four” independent, certified public accountant (e.g., Deloitte, KPMG, PWC or EY), designated by the other Party and reasonably acceptable to the audited Party, at reasonable times and upon reasonable notice, to audit the books and records maintained by or on behalf of the audited Party pursuant to Section 10.11 to ensure the accuracy of all reports and payments made by such audited Party hereunder; *provided*, that such examinations must be of a reasonably tailored scope, and may not: (a) be conducted more than [**] period (unless a previous audit during such [**] period revealed an underpayment with respect to such period); or (b) be repeated for any [**]. The independent, certified public accountant shall report to Verve and Lilly only the amounts of Net Sales, Royalties, Verve Costs, Lilly Costs and Gross Margin amounts for the applicable time period, along with the amount of any payments that became due and payable for such period. Except as provided below, the cost of any such audit shall be borne by the auditing Party, unless the audit reveals a variance of more than [**] percent ([**]%) from the reported amounts or [**] Dollars (\$[**]), whichever is greater, in which case the audited Party shall bear the cost of the audit. If such audit concludes that: (i) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts with interest from the date originally due as provided in Section 10.5 or (ii) excess payments were made by the audited Party, the auditing Party shall reimburse such excess payments, in each case ((i) or (ii)), within [**] after the date on which such audit is completed by the auditing Party.

10.12.2 Upon request of Verve, at Verve’s expense, Lilly will have Lilly’s external financial auditor (provided such external financial auditor is a “Big Four” independent, certified public accountant (i.e., Deloitte, KPMG, PWC, or EY)) provide confirmation to Verve [**].

10.12.3 The receiving Party shall treat all information subject to review under

this Section 10.12 in accordance with Article 14 and the Parties shall cause the auditors referenced in this Section 10.12 to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

10.13. Method of Payment; Currency Conversion. Unless otherwise agreed by the Parties, all payments due under this Agreement shall be paid in Dollars by wire transfer or electronic funds transfer of immediately available funds to an account designated by the payee; *provided*, however, that Lilly shall only be required to disburse funds to the payee’s jurisdiction of incorporation or to a jurisdiction in which the payee has a significant business presence. When conversion of payments from any currency other than Dollars is required, Lilly’s then-current standard exchange rate methodology will be employed for the translation of foreign currency

sales into Dollars; provided, that this methodology is used by Lilly in translation of its foreign currency operating results, is consistent with U.S. GAAP, is audited by Lilly's independent certified public accountants in connection with the audit of the consolidated financial statements of Lilly, and is used for external reporting of foreign currency operating results.

ARTICLE 11

INTELLECTUAL PROPERTY

11.1.Ownership. As between the Parties: (a) each Party shall own and retain all right, title and interest in and to all of its Background IP; (b) Verve shall own and retain all right, title and interest in and to the Verve Sole IP; (c) Lilly shall own and retain all right, title and interest in and to the Lilly Sole IP; and (d) all right, title and interest in Joint IP shall be owned jointly by Lilly and Verve.

11.1.1 Lilly shall, and does hereby, assign its right, title and interest in any and all Verve Sole IP (including all rights of action and claims for damages and benefits arising due to past and present infringement of such rights) to Verve.

11.1.2 Verve shall, and does hereby, assign its right, title and interest in any and all Lilly Sole IP (including all rights of action and claims for damages and benefits arising due to past and present infringement of such rights) to Lilly.

11.2.Use of Joint IP. Subject to the terms of this Agreement: (a) each Party shall have the right to practice, grant licenses under, and transfer any Joint IP (subject to the licenses granted Lilly hereunder); (b) neither Party shall have any obligation to account to the other for profits or to obtain any approval of the other Party to license or Exploit any Joint IP, including by reason of joint ownership thereof; and (c) each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting; provided that, in Exploiting or licensing such Joint IP, neither Party shall have any right or license to any Background IP, sole IP or other Intellectual Property Rights of the other Party, in each case, not otherwise expressly granted elsewhere in this Agreement.

11.3.United States Law. Unless otherwise expressly provided in this Agreement, as between the Parties, ownership of inventions shall be based on inventorship, and ownership of Know-How shall be based on the Party that Generated it. The determination of inventorship shall be made in accordance with the United States patent law without regard to conflict of law, irrespective of where or when such invention occurs.

11.4. Assignment Obligation. Each Party shall cause its and its Affiliates' and its and their Sublicensees' employees and representatives, and shall use Commercially Reasonable Efforts to cause any Third Party who performs any activities on behalf of such Party under this Agreement or who Generates any Know-How that is subject to this Agreement by or on behalf of such Party or any of its Affiliates or its or their Sublicensees under this Agreement, to [**] any Know-How consistent with the obligations under this Agreement resulting therefrom (including all rights of action and claims for damages and benefits arising due to past and present infringement of such Know-How) to such Party or any of its Affiliates or Sublicensees, except where Applicable Law requires otherwise and except in the case of governmental or not-for-profit institutions that have standard policies against such an assignment (in which case a suitable license, or right to obtain such a license, shall be obtained); *provided*, that, to the extent [**]. The Parties will work together in good faith to identify and discuss Know-How material to Exploitation of a Licensed Product Generated in the course of activities under this Agreement and Verve shall disclose Lilly IP Improvements made by or on behalf of Verve (or its Affiliates) to Lilly and Lilly shall disclose Verve IP Improvements made by or on behalf of Lilly (or its Affiliates or its or their Sublicensees) to Verve.

11.5. Inventor's Remuneration. Each Party shall be solely responsible for any remuneration that may be due such Party's inventors under any applicable inventor remuneration laws.

11.6. Independent Development. Subject to the licenses, interests and obligations of exclusivity granted hereunder, nothing in this Agreement shall be construed as limiting either Lilly's or Verve's right to research, develop, improve and in-license technology.

11.7. In-Licensed Technology.

11.7.1 Existing In-Licensed Technology. If any Existing In-Licensed Technology licensed under the [**] Agreement is encompassed by a Research and Development Plan as of the Execution Date or otherwise incorporated under a Research and Development Program pursuant to this Section 11.7.1, then Lilly shall reimburse Verve an amount [**]. Lilly may request to remove or exclude any such Existing In-Licensed Technology from a Research and Development Program, in which event, (i) the Parties will discuss in good faith whether such removal or exclusion can be reasonably achieved, and if so, the Parties shall agree upon a revised corresponding Research and Development Plan (for clarity, Verve shall not withhold its consent to such revisions if such removal or exclusion is reasonably feasible from a technical perspective), and (ii) following the Parties' agreement upon revisions to the Research and Development Plan, removal or exclusion shall be reflected by Verve in the Existing License Share, and upon such removal or exclusion, such Existing In-Licensed Technology shall be deemed to not be included in the Licensed Patents or Licensed Know-How.

11.7.2 Future In-Licensed Technology.

(a) If either Party identifies any Patents or Know-How Controlled by a Third Party that such Party believes would be necessary or useful for Research, Development or Commercialization of a Licensed Product, [**].

(b) If Verve or Lilly provides the notice set forth in Section 11.7.2(a), the Parties will discuss in good faith procurement of such Patents or Know-How, the terms under which it would be acceptable to obtain a license to such Patents or Know-How as it relates to Licensed

Products, and the details of any amendment (if not already within the scope of such Research and Development Plan) that would be needed to include such Patents or Know-How within the applicable Research and Development Plan. [**].

(c) [**].

(d) With respect to each Future In-Licensed Technology Agreement for which Lilly elects a sublicense, Lilly shall reimburse Verve an amount equal to [**].

11.7.3 *Payment of [**]*. Lilly will pay the [**] to Verve as follows:

(a) [**].

(b) [**].

(c) [**].

(d) [**].

(e) [**].

11.8. Patent Prosecution and Maintenance.

11.8.1 Rights to Prosecute and Maintain Patents. As between the Parties:

(a) Lilly shall have (i) before Phase 2 Assumption with respect to a Licensed Product, the secondary right, but not the obligation, to Prosecute and Maintain any Product Patent with respect to such Licensed Product, (ii) after Phase 2 Assumption with respect to a Licensed Product, the first right, but not the obligation, to Prosecute and Maintain any Product Patent with respect to such Licensed Product, (iii) the sole right, but not the obligation, to Prosecute and Maintain any Lilly Sole IP, and (iv) the first right, but not the obligation, to

Prosecute and Maintain any Joint Patent, in each case (i) through (iv), at Lilly's sole cost and expense.

(b) Verve shall have (i) before Phase 2 Assumption with respect to a Licensed Product, the first right, and but not the obligation, to Prosecute and Maintain any Product Patent with respect to such Licensed Product, (ii) after Phase 2 Assumption with respect to a Licensed Product, the secondary right, but not the obligation, to Prosecute and Maintain any Product Patent with respect to such Licensed Product, (iii) the sole right, but not the obligation, to Prosecute and Maintain any Verve Sole IP, excluding any Product Patent; *provided* that Prosecution and Maintenance of any Patent captured by the foregoing [**], and (iv) the secondary right (as described in Section 11.8.2), but not the obligation, to Prosecute and Maintain any Joint Patent, in each case (i) through (iv), at Verve's sole cost and expense.

11.8.2Secondary Right with Respect to Joint Patents and Product Patents. Each Party shall notify the other Party as to any final decision not to initiate or continue Prosecution and Maintenance of any Joint Patent or Product Patent that the other Party has the right to Prosecute and Maintain under Section 11.8.1 at least [**] prior to any filing or payment due date, or any other due date that requires action to avoid loss of rights, in connection with such Joint Patent or Product Patent. Thereafter, the Party with the secondary right may, upon written notice to the other Party, Prosecute and Maintain such Joint Patent or Product Patent worldwide,

at its sole cost and expense, using counsel of its choice. If Verve has assigned any such Patent to Lilly under this Agreement, Lilly shall, upon written notice from Verve, assign such Patent back to Verve. However, if Lilly declines to prosecute Joint Patent or Product Patent to preserve the validity or enforceability of another royalty bearing Patent, which provides market exclusivity for the Licensed Product, Verve will discuss in good faith with Lilly the Prosecution and Maintenance of such Joint Patent or Product Patent to avoid reasonably impairing exclusivity for the Licensed Product.

11.8.3No Disclosure of Confidential Proprietary Information. Neither Party may file a Patent application that includes Confidential Proprietary Information of the other Party without the other Party's prior written consent. Notwithstanding the foregoing, (a) Lilly shall be able to use and disclose [**], and (b) Verve shall be able to use and disclose [**].

11.8.4Cooperation of the Parties; Patent Working Group. The JSC shall establish a patent Working Group (the "**Patent Working Group**") within [**] following the Effective Date (which shall meet with a frequency determined by the JSC). Through the Patent Working Group, the Parties will (a) keep each other reasonably informed as to all material filings, responses or

submissions regarding any Prosecution and Maintenance with respect to any Joint Patent, Product Patent, and any patent that includes composition of matter claims specific to a Development Molecule, Candidate, or a Licensed Product, and any Verve Genus Claim Patent or Mix Patent, (b) exchange copies of any such material filings, responses, and submissions received from or proposed to be sent to any patent authority, court, or other tribunal sufficiently in advance of submitting such communications, filings and submissions, and (c) discuss in good faith any foreign filing strategies. Each Party shall consider in good faith timely-provided comments from the other Party with respect to the foregoing (and, any arising disputes shall be escalated to the JSC), provided that the Party responsible for Prosecuting and Maintaining such Patents shall have final decision making authority with respect to such communications, filings and submissions. Each Party shall cooperate fully with the other Party in the Prosecution and Maintenance of Patents under this Section 11.8, including by: (x) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, to enable the other Party to apply for and to Prosecute and Maintain such Patents in such country; and (y) promptly informing the other Party of any material matters coming to such Party's attention that may affect the Prosecution and Maintenance of any such Patent. Each Party will use reasonable efforts via good faith consultation to avoid creating potential issues in Prosecution and Maintenance of Patents under this Section 11.8.

11.8.5 Assignment. Verve may (in its sole discretion) assign to Lilly its rights in Patents that are Joint Patents or Product Patents. In addition, without otherwise affecting its rights under this Agreement, upon Lilly's written request made after Phase 2 Assumption, Verve will assign to Lilly its rights in Patents that are Product Patents. Any Patent assigned to Lilly under this Section 11.8.5 shall continue to be deemed a Licensed Patent for all purposes under this Agreement, including for purposes of calculating the Royalty Term. To the extent that any Joint Patents or Product Patents are assigned to Lilly under this Section 11.8.5: (a) Lilly agrees to Prosecute and Maintain any such assigned Patents in good faith and without taking or refraining from taking any action for the purpose of reducing the Royalty Term; (b) Lilly must limit prosecution of claims within any such assigned Joint Patents or Product Patents only to **[**]**; (c) Lilly shall promptly notify Verve as to any final decision not to initiate or continue Prosecution and Maintenance of any Joint Patent or Product Patent that Lilly has the right to Prosecute and Maintain, and, upon Verve's request after receipt of such notice, Lilly will promptly assign (and hereby does assign) any such Joint Patent or Product Patent back to Verve but Verve's rights to

continue prosecution of such IP shall be limited as described in the last sentence of Section 11.8.2; and (d) upon Verve's request after expiration or termination of this Agreement for any reason in whole or in part, Lilly will promptly assign (and hereby does assign) any such Joint Patent or Product Patent back to Verve.

11.8.6 *Mix Patents*. [**], to (a) [**], and (b) [**].

11.9. Infringement or Misappropriation by Third Parties.

11.9.1 *Notice*. Each Party shall notify the other within [**] of becoming aware of any alleged or threatened (in writing) infringement by a Third Party of any Patents of the other Party, in each case, in connection with the [**] (collectively, “**Infringement**”).

11.9.2 **Rights to Initiate Proceedings**. As between the Parties:

(a) Lilly shall have (i) the sole right, but not the obligation, to initiate any proceedings or take other appropriate actions against Infringement, or defend against any challenge, of Lilly Sole IP, and (ii) the first right, but not the obligation, to initiate any proceedings or take other appropriate actions against Infringement of any [**], in each case (i) and (ii), at Lilly’s sole Cost and expense. Verve may (in its sole discretion) assign to Lilly its rights under Patents referenced in this section, and in such event, the provisions of Section 11.8.5(a) through (d) will apply with respect to any such assigned Patent (*mutatis mutandis*).

(b) Verve shall have (i) the sole right, but not the obligation, to initiate any proceedings or take other appropriate actions against Infringement, or defend against any challenge, of Verve Sole IP (excluding any Product Patent), and (ii) the second right, but not the obligation, to initiate any proceedings or take other appropriate actions against Infringement, or defend against any challenge, of [**], in each case (i) and (ii), at Verve’s sole cost and expense. [**].

11.9.3 *Verve’s Secondary Right with Respect to [**]*. If Lilly fails to institute or prosecute an Infringement, or defend against any challenge, in each case as set forth in Section (a)(ii), within a period of [**] after the first notice of the applicable Infringement under Section 11.9.1, then Verve may, upon written notice to Lilly, institute, prosecute and control such Infringement, or defend against such challenge, at its sole cost and expense using counsel of its choice; provided that [**].

11.9.4 *Cooperation*. At the request and sole expense of the Party bringing an action under this Section 11.9, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required by Applicable Law to pursue such action.

11.9.5 *Settlement; Recovery*. Unless otherwise set forth herein, the controlling Party shall have the right to settle any Infringement pursuant to this Section 11.9; provided, that [**]. Any recovery realized as a result of any Infringement described in this Section 11.9 (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their costs

and expenses in making such recovery, which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses. Any remainder after such reimbursement is made shall [**].

11.9.6 *Biosimilar Applications*. Lilly shall have the first right, but not the

obligation, to prosecute and manage any litigation with respect to Generic/Biosimilar Equivalents involving [**] and any proceedings associated therewith, including any invalidity, unpatentability or unenforceability challenges, oppositions and post-grant proceedings in connection therewith. If either Party receives a notice or a copy of an application submitted to the FDA or its foreign counterpart for a Generic/Biosimilar Equivalent (a “**Biosimilar Application**”) for which a Licensed Product is a “reference product” as such term is used in Section 351(i)(4) of the PHSA, or an equivalent under its foreign counterpart, whether or not such notice or copy is provided under any Applicable Laws, either Party shall, within [**], notify and provide the other Party copies of such notice or communication to the extent permitted by Applicable Law. Lilly shall carry out any such rights and responsibilities of the “reference product sponsor,” as defined in Section 351(l)(1)(A) of the PHSA, for purposes of such Biosimilar Application, including bringing an action for patent infringement under Section 351(l)(6) of the PHSA based on [**] Covering the Generic/Biosimilar Equivalent. If requested by Lilly, Verve shall seek to obtain access to the Biosimilar Application and related confidential information, including in accordance with Section 351(l)(1)(B)(iii) of the PHSA, if applicable. If permitted pursuant to Applicable Law, upon Lilly’s request, Verve shall assist Lilly in identifying and listing [**] Patents pursuant to Section 351(l)(1)(3)(A) or Section 351(l)(7) of the PHSA, in preparing, pursuant to section 351(l)(3)(C) of the PHSA, a detailed statement regarding the reference product sponsor’s opinion that any such patent will be infringed and a response to the statement by the filer of the Biosimilar Application concerning validity and enforceability, in negotiating with the filer of the Biosimilar Application pursuant to Section 351(l)(4) of the PHSA, and in selecting Patents for and conducting litigation pursuant to Section 351(l)(5), Section 351(l)(6), and Section 351(l)(9) of the PHSA, to the extent applicable, and shall cooperate with Lilly in responding to relevant communications with respect to such lists and statements from the filer of the Biosimilar Application. Upon Lilly’s request, Verve shall assist in seeking an injunction against any commercial marketing by the filer of a Biosimilar Application as permitted pursuant to Section 351(l)(8)(B) of the PHSA or in filing an action for infringement against the filer of such Biosimilar Application. Notwithstanding anything to the contrary, this Section 11.9.6 will not be construed to provide rights to enforce [**] other than a [**] unless otherwise agreed between the Parties including with respect to the good faith consideration contemplated under Section 11.9.2.

11.10. Defense and Settlement of Third Party Claims. Each Party shall promptly notify the other in writing of: (a) [**]; or (b) [**]. Neither Party may settle any patent infringement litigation under this Section 11.10 in a manner that [**] or [**]. Nothing in this Section 11.10 will limit any indemnification rights or obligations of a Party under Section 13.1.

11.11. Patent Extension. Lilly shall have the sole right, and Verve shall have no right, to obtain patent term restoration in any country in the Territory under any statute or regulation equivalent or similar to 35 U.S.C. § 156, where applicable to a Licensed Product; *provided, however,* that Lilly may not elect to extend a Patent Controlled by Verve or its Affiliates that is not a [**] Patent without Verve's prior written consent.

11.12. Patent Listings. As between the Parties, Lilly shall have the sole right to make all filings with Regulatory Authorities in the Territory with respect to the [**] Patents, including as required or allowed (a) in the United States, in the FDA's Orange Book or Purple Book and (b) in the European Union, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents. Verve shall, at Lilly's sole expense, (i) provide Lilly a list of [**] Patents Covering the Licensed Products and other information necessary or reasonably useful to enable Lilly to make such filings with Regulatory Authorities and (ii) cooperate with Lilly's reasonable requests in connection therewith, including executing any

documents, meeting any submission deadlines, in each case (i) and (ii), to the extent required or permitted by Applicable Law.

11.13. CREATE Act. It is the Parties' intention that this Agreement is a "joint research agreement" as that phrase is defined in 35 U.S.C. § 102(c) as amended by the Cooperative Research and Technology Enhancement (CREATE) Act, including the provisions of 35 U.S.C. § 102(b)(2)(c). The Parties agree to cooperate and to take reasonable actions to maximize the protections available for the Licensed Products under such safe harbor provisions.

11.14. Trademarks. Lilly shall have the right to select, and will be free, in its sole discretion, to use and to register in any trademark office in the Territory, any trademark for use with a Licensed Product (the "**Licensed Product Trademarks**"). As between the Parties, Lilly shall own all right, title and interest in and to any such Licensed Product Trademarks adopted by Lilly for use with Licensed Product, and is responsible for the registration, filing, maintenance and enforcement thereof.

ARTICLE 12

REPRESENTATIONS, WARRANTIES AND COVENANTS

12.1.Mutual Representations and Warranties. Each of Lilly and Verve represent and warrant, as of the Execution Date, that:

12.1.1it is duly organized and validly existing under the Applicable Laws of the jurisdiction of its incorporation or formation, as applicable, has full corporate, limited liability company or other power and authority, as applicable, to enter into this Agreement and to carry out the provisions hereof, and has sufficient facilities, experienced personnel or other capabilities (including via Affiliates and/or Third Parties) to enable it to perform its obligations under this Agreement;

12.1.2it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the individual executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate, limited liability company or other action, as applicable; and

12.1.3this Agreement is legally binding upon it and enforceable in accordance with its terms (except as the enforceability thereof may be limited by bankruptcy, bank moratorium or similar laws affecting creditors' rights generally and laws restricting the availability of equitable remedies and may be subject to general principles of equity whether or not such enforceability is considered in a proceeding at law or in equity) and the execution, delivery and performance of this Agreement by it have been duly authorized by all necessary corporate action and do not and will not: (a) conflict with, or constitute a default or result in a breach under, any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, or violate any Applicable Law; or (b) require any consent or approval of its stockholders or similar.

12.2.Verve Representations and Warranties. Verve represents, warrants and covenants to Lilly that, as of the Execution Date:

12.2.1*No Grants that Conflict with this Agreement.* Verve and its Affiliates have not granted any rights (or other encumbrances) to any Third Party that prevent or conflict

with the rights granted to Lilly hereunder.

12.2.2*Control over Know-How and Patents.* Verve has Control over all Patents and Know-How owned by it or its Affiliates that are necessary or reasonably useful for the Exploitation of Licensed Products in the Field, as known to be contemplated by this Agreement.

12.2.3*Existing Patents.*

(a) All Patent rights owned by Verve issued or subject to a pending application for issuance that are existing and [**] are listed on Schedule 12.2.3(a) (the “**Existing Patents**”).

(b) All Existing Patents: (i) are to the extent issued, subsisting and not invalid or unenforceable, in whole or in part, or confer a valid right to claim priority thereto; (ii) are solely and exclusively owned by, or exclusively licensed to, Verve, free of any encumbrance, lien or known (to Verve’s Knowledge) claim of ownership by any Third Party that impairs the rights and licenses granted to Lilly under this Agreement; (iii) are to the extent subject to a pending application for issuance, [**]; and (iv) are filed and maintained in accordance with applicable Patent office rules, and all applicable fees applicable thereto have been paid on or before any final due date for payment.

(c) [**].

(d) The Existing Patents represent all Patents owned by Verve and its Affiliates that Cover any material aspects of the [**] being discussed by the Parties as of the Execution Date.

(e) [**].

12.2.4 Third Party Agreements. The Existing In-License Agreements constitute all agreements from Third Parties pursuant to which Verve Controls any Licensed Patents and Licensed Know-How anticipated by Verve to be used in the Research and Development Program. The licenses granted to Verve under the Existing In-License Agreements are, to the extent that the applicable rights are sublicensed to Lilly hereunder, in full force and effect. [**]. To Verve’s Knowledge, the counterparties to the Existing In-License Agreement are [**].

12.2.5 [] Relating to Intellectual Property.** Verve has not received any written notice of [**] subject to the licenses granted to Lilly pursuant to Article 8; [**].

12.2.6 No Infringement. To Verve’s Knowledge, the composition of [**] or [**] alone (individually and not in combination or part of a formulation with other components) does not infringe any issued Patent of any Third Party.

12.2.7 Other Material Claims and Actions. There are no claims, actions, or proceedings pending [**], which if adversely decided, would, individually or in the aggregate, have a material adverse effect on, or prevent Verve’s ability to conduct the Research or Development, or to grant the licenses or rights granted to Lilly under this Agreement.

12.2.8 Assignment by Employees, Agents and Consultants. Verve has obtained from each of its current employees, consultants and contractors, in each case who perform research or

development activities pursuant to this Agreement, written agreements containing obligations of confidentiality and non-use and an assignment to Verve of all inventions (and all of such

Person's rights thereto) for which Verve or Lilly is intended to have ownership or license rights under this Agreement such that no such employee, contractor or consultant shall retain any rights to such inventions that would prevent or conflict with Lilly's rights of ownership or use of such inventions contemplated by this Agreement.

12.2.9 *No Government Funding.* The inventions claimed or covered by the [**] Patents: (a) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by, or otherwise using the resources of, any Governmental Authority (whether of the U.S., the United Kingdom, or otherwise); (b) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e) and (c) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. Part 401 (the Bayh-Dole Act).

12.2.10[**].

12.3. Mutual Covenants.

12.3.1 *Debarment.* Each Party represents, warrants and covenants to the other Party that neither it nor its officers, employees, agents, consultants or any other person used by such Party in the performance of the respective research and development activities under this Agreement is: (a) debarred or disqualified under the FD&C Act; (b) listed by any government or regulatory agencies as ineligible to participate in any government healthcare programs or government procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)), or excluded, debarred, suspended or otherwise made ineligible to participate in any such program; or (c) convicted of a criminal offense related to the provision of healthcare items or services, or is subject to any such pending action. Each Party will not during the Term knowingly, employ or use, directly or indirectly, including through Affiliates the services of any such person. In the event that either Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such Party, directly or indirectly, including through Affiliates or, in the case of Lilly, Sublicensees, which directly or indirectly relate to activities contemplated by this Agreement, such Party shall promptly notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

12.3.2 Protection of Information. Each Party agrees that during the Term of this Agreement, and without limiting its obligations hereunder, each Party shall implement technical and organizational measures to protect all information under the Agreement that are appropriate and that provide no less protection than both (i) good industry practice (*i.e.*, in accordance with ISO 27001 and/or similar industry standards) and (ii) such Party's measures to protect its own information of a similar nature or importance.

12.4. Compliance.

12.4.1 Compliance with this Agreement. Each of the Parties shall cause their respective Affiliates to comply in all material respects with the terms of this Agreement to the extent applicable to such Affiliates.

12.4.2 Compliance with Applicable Laws. Each Party covenants to the other that in the performance of its obligations under this Agreement, such Party shall comply with, and shall

cause its Affiliates and its Affiliates' employees and contractors to comply with all Applicable Laws. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any Applicable Laws.

12.4.3 Compliance with Party-Specific Regulations. In carrying out their respective obligations under this Agreement, the Parties agree to cooperate with each other as may reasonably be required to help ensure that each is able to fully meet its obligations with respect to all judgments, decrees, orders or similar decisions issued by any Governmental Authority specific to a Party, and all consent decrees, corporate integrity agreements, or other agreements or undertakings of any kind by a Party with any Governmental Authority, in each case as the same may be in effect from time to time and applicable to a Party's activities contemplated by this Agreement (the **"Party-Specific Regulations"**). Each Party shall be responsible for providing the other Party with any Party-Specific Regulations applicable to the other Party, including any updates to such Party-Specific Regulations, and the covenant in the preceding sentence shall only apply to the extent such Party-Specific Regulations and any updates thereto have been provided to the other Party. Neither Party shall be obligated to pursue any course of conduct that would result in such Party being in material breach of any Party-Specific Regulation applicable to it; *provided* that in the event that a Party refuses to fulfill its obligations under this Agreement in any material respect on such basis, the other Party shall have the right to terminate this Agreement in accordance with Section 16.2; however, under such circumstances, such termination, including the applicable effects of such termination set forth in Section 16.6, shall be the sole remedy for such terminating Party and such terminating

Party shall not be entitled to any other remedy under law or equity. All Party-Specific Regulations are binding only in accordance with their terms and only upon the Party to which they relate.

12.4.4 Compliance with Internal Compliance Codes. All Internal Compliance Codes shall apply only to the Party to which they relate. The Parties agree to cooperate with each other to help ensure that each Party is able to comply with the substance of its respective Internal Compliance Codes and, to the extent practicable, each Party shall operate in a manner consistent with its Internal Compliance Codes applicable to its performance under this Agreement. **“Internal Compliance Codes,”** as used in this Section 12.4.4, means a Party’s internal policies and procedures intended to ensure that a Party complies with Applicable Laws, Party-Specific Regulations, and such Party’s internal ethical, medical and similar standards.

12.4.5 Compliance with Anti-Corruption Laws. In connection with this Agreement, the Parties shall comply with all applicable local, national, and international laws, regulations, and industry codes dealing with government procurement, conflicts of interest, corruption or bribery, including, if applicable, the U.S. Foreign Corrupt Practices Act of 1977, as amended, and any laws enacted to implement the Organisation of Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions.

12.4.6 Compliance with U.S. Open Payments Law. Pursuant to 42 U.S.C. § 1320a-7h, as amended (the **“Open Payments Law”**), certain Applicable Manufacturers must publicly disclose certain payments or other transfers of value to Covered Recipients (as such terms are defined in the Open Payments Law). Each Party is responsible for compliance with the Open Payments Law in regard to the reporting of any of their own payments or other transfers of value related to this Agreement, as applicable. Upon request and to the extent related to this Agreement, either Party shall provide such additional information and assistance that the other Party reasonably

requires for compliance with the Open Payments Law and to address any claims raised by a Covered Recipient relating to the accuracy and completeness of any reported transfers of value.

12.4.7 Compliance with Privacy Laws. In connection with this Agreement, Verve and its Affiliates, and any Person acting for or on its or their behalf, will comply with all Applicable Laws with respect to data protection and privacy laws with respect to the receipt, collection, compilation, use, storage, processing, sharing, safeguarding, security (technical, physical and administrative), disposal, destruction, disclosure, or transfer (including cross-border) of Personal Information, including providing any notice, obtaining any consent or prior authorization, and conducting any assessment required under Applicable Laws.

12.4.8 Prohibited Conduct. Without limiting the other obligations of the Parties set forth in this Section 12.4.8, each Party covenants to the other that, as of the Execution Date and in the performance of its obligations under this Agreement through the expiration or termination of this Agreement, such Party and, to its knowledge, its Affiliates and its Affiliates' employees and contractors, in connection with the performance of their respective obligations under this Agreement, have not made, offered, given, promised to give, or authorized, and will not make, offer, give, promise to give, or authorize, any bribe, kickback, payment or transfer of anything of value, directly or indirectly through Third Parties, to any Government Official for the purpose of: (a) improperly influencing any act or decision of the Person or Government Official; (b) inducing the Person or Government Official to do or omit to do an act in violation of a lawful or otherwise required duty; (c) securing any improper advantage; or (d) inducing the Person or Government Official to improperly influence the act or decision of any organization, including any government or government instrumentality, to assist any Party in obtaining or retaining business for or with, or directing business to, any Person, including either Party. For the purpose of this Section 12.4.8 **"Government Official"** means: (x) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital; (y) any candidate for political office, any political party or any official of a political party; or (z) any Person acting in an official capacity on behalf of any of the foregoing.

12.4.9 Trade Sanctions.

(a) Each Party agrees to comply with all applicable trade sanctions and export control laws and regulations, including where applicable the U.S. trade sanctions administered by the U.S. Treasury Department's Office of Foreign Assets Control (31 C.F.R. Part 501 et seq.), the U.S. Export Administration Regulations (15 C.F.R. Part 734 et seq.), and European Union trade sanctions and export laws (including without limitation Council Regulation (EC) No. 428/2009 (as amended)).

(b) Each Party represents and warrants that it is not, nor are any of its directors, executive officers, agents, shareholders or any person having a controlling interest in such Party, (i) a person targeted by trade or financial sanctions under the laws and regulations of the United Nations, the United States, the European Union and its Member States, the United Kingdom or any other jurisdiction that is applicable to the licenses or rights granted, or activities to be performed, under this Agreement, including but not limited to persons designated on the U.S. Department of the Treasury, Office of Foreign Assets Control's List of Specially Designated Nationals and Other Blocked Persons and Consolidated Sanctions List, the U.S. State

Department's Non-proliferation Sanctions Lists, the UN Financial Sanctions Lists, the EU's Consolidated List of Persons, Groups and Entities Subject to EU Financial Sanctions, and the UK HM Treasury Consolidated Lists of Financial Sanctions Targets; (ii) incorporated or headquartered in, or organized under the laws of, a territory subject to comprehensive U.S. sanctions (each, a "**Sanctioned Territory**") (currently, Cuba, Iran, Crimea, North Korea and Syria, but subject to change at any time) or (iii) directly or indirectly owned or controlled by such persons (together "**Restricted Person**"). Each Party further represents and warrants that it shall notify the other Party in writing immediately if it or any of its directors, executive officers, agents, shareholders or any person having a controlling interest in it becomes a Restricted Person or if Verve becomes directly or indirectly owned or controlled by one or more Restricted Persons.

(c) Lilly agrees that no Licensed Products (or any components thereof) will be used, sold, transferred, or otherwise made available, directly or indirectly, to or for the benefit of a Sanctioned Territory or Restricted Person without the prior written approval from Verve, other than in compliance with Applicable Law.

12.4.10*Compliance with In-License Agreements.* Verve shall comply in all material respects with the terms of the Existing In-License Agreements and Future In-Licensed Technology Agreements and will maintain such agreements in full force and effect for the term of the licensed Intellectual Property Rights, subject to termination with Lilly's consent in accordance with Section 12.2.4.

12.4.11*Disclaimer.* Except as otherwise expressly set forth in this Article 12, neither Party makes any representations or extends any warranties of any kind, either express or implied, including warranties of merchantability, quality, fitness for a particular purpose, noninfringement, or validity of patent claims. Nothing in this Agreement shall be construed as a representation made or warranty given by either Party that either Party will be successful in obtaining any Patents or that any Patents will issue based on a pending application. Without limiting the respective rights and obligations of the Parties expressly set forth herein, each Party specifically disclaims any guarantee that any Licensed Products will be successful, in whole or in part.

ARTICLE 13

INDEMNIFICATION

13.1. Indemnity.

13.1.1 *By Verve*. Subject to Section 13.1.3, Verve shall defend, indemnify and hold harmless Lilly and its Affiliates, and their respective directors, officers, employees, and agents (each, a **"Lilly Indemnatee"**) from and against any and all costs, fees, expenses, losses, liabilities, and damages, including reasonable legal expenses and attorneys' fees (collectively, **"Losses"**) to which any Lilly Indemnatee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (a **"Claim"**) to the extent such Claim and Losses arise out of: (a) the gross negligence or willful misconduct of Verve or its Affiliates in connection with performance of its activities under this Agreement; (b) the breach of this Agreement or the representations, warranties, and covenants made hereunder by Verve, (c) [**], and (d) [**]; except, in each case, to the extent such Losses result from matters described in clause (a), (b), or (c) of Section 13.1.2.

13.1.2 *By Lilly*. Subject to Section 13.1.3, Lilly shall defend, indemnify and hold harmless Verve, its Affiliates, and their respective directors, officers, employees and agents (each, a **"Verve Indemnatee"**) from and against any and all Losses to which any Verve Indemnatee may become subject as a result of any Claim to the extent such Claim and Losses arise out of: (a) the gross negligence or willful misconduct of Lilly, its Affiliates, or their respective Sublicensees in connection with performance of its or their activities under this Agreement; (b) the breach of this Agreement or the representations, warranties and covenants made hereunder by Lilly; or (c) [**]; except, in each case, to the extent such Losses result from matters subject to clauses (a), (b), (c) or (d) of Section 13.1.1.

13.1.3 *Procedure*. A Party that intends to claim indemnification under this Article 13 (the **"Indemnatee"**) shall promptly notify the Indemnitor (the **"Indemnitor"**) in writing of any Claim in respect of which the Indemnatee intends to claim such indemnification. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 13 if and to the extent the Indemnitor is actually and materially prejudiced thereby. The Indemnitor has sole control of the defense or settlement thereof. The Indemnatee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification. The Indemnatee may participate at its expense in the Indemnitor's defense of and settlement negotiations for any Claim with counsel of the Indemnatee's own selection. The Indemnitor shall not settle any Claim without the prior written consent of the Indemnatee, not to be unreasonably withheld, conditioned or delayed. So long as the Indemnitor is actively defending the Claim in good faith, the Indemnatee shall not settle or compromise any such Claim without the prior written consent of the Indemnitor. If the Indemnitor does not assume and conduct the defense of the Claim as provided above: (a) the Indemnatee may defend against, consent to the entry of

any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnitee may deem reasonably appropriate (and the Indemnitee need not consult with, or obtain any consent from, the Indemnitor in connection therewith); and (b) the Indemnitor shall remain responsible to indemnify the Indemnitee as provided in this [Article 13](#).

13.2. Insurance. During the Term, each Party shall maintain such types and amounts of liability insurance (including self-insurance) as is normal and customary in the industry generally for similarly situated parties and adequate to cover its obligations under this Agreement, and Verve will upon request provide Lilly with a certificate of insurance in that regard, along with any amendments and revisions thereto.

ARTICLE 14

CONFIDENTIALITY

14.1. Confidential Proprietary Information.

14.1.1 Confidential Proprietary Information. In connection with this Agreement, each Party may disclose to the other Party certain of such Party's nonpublic technical, business or other confidential information, whether prior to, on, or after the Effective Date, including: (a) any unpublished Patents; and (b) any information regarding the scientific, regulatory or business affairs or other activities (such confidential information, such Party's "**Confidential Proprietary Information**"). Without limiting the foregoing, the terms of this Agreement are Confidential Proprietary Information and shall be treated confidentially by the Parties, subject to

the exceptions set forth in [Section 14.1.4](#). Without limiting the foregoing, until such time as the applicable information has become available to the public in accordance with this Agreement, the Parties agree that (i) the collective results of the Research and Development Program (the "**Program Results**"), (ii) existing information related to a Licensed Product, either disclosed to either Party prior to or after the Effective Date, and (iii) all Regulatory Filings with respect to a Licensed Product, each (i) through (iii) will be treated confidentially by each of the Parties, and neither Party shall disclose the Program Results except pursuant to [Section 14.1.4](#). Information exchanged by the Parties pursuant to the Confidentiality Agreement shall be treated as Confidential Proprietary Information under this Agreement and governed by the terms of this Agreement.

14.1.2 Restrictions. A Party (the "**Receiving Party**") that receives or otherwise learns Confidential Proprietary Information of the other Party (the "**Disclosing Party**") shall keep all the Disclosing Party's Confidential Proprietary Information in confidence with the same degree of

care with which the Receiving Party holds its own confidential information (but in no event less than a commercially reasonable degree of care). A Receiving Party shall not use the Disclosing Party's Confidential Proprietary Information except in connection with the performance of its obligations and exercise of its rights under this Agreement.

14.1.3*Exceptions.* The obligations of confidentiality and restriction on use of Confidential Proprietary Information under Section 14.1.2 do not apply to any information that the Receiving Party can prove by competent written evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party, generally known or available to the public; (b) is known by the Receiving Party at the time of receiving such information, other than by previous disclosure of the Disclosing Party, or its Affiliates, employees, agents, consultants, or contractors; (c) is hereafter furnished to the Receiving Party without restriction by a Third Party who has no obligation of confidentiality or limitations on use with respect thereto, as a matter of right; or (d) is independently discovered or developed by the Receiving Party without the use of or reference to Confidential Proprietary Information belonging to the Disclosing Party. Specific information shall not be deemed to be within any of the foregoing exclusions merely because it is embraced by more general information falling within those exclusions.

14.1.4*Permitted Disclosures.* The Receiving Party may disclose Confidential Proprietary Information belonging to the Disclosing Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) made by or on behalf of the Receiving Party to a Patent authority as may be reasonably necessary or useful for purposes of Prosecution and Maintenance of Patents as permitted by this Agreement; *provided*, that [**];

(b) made by or on behalf of the Receiving Party to Regulatory Authorities as required in connection with any Regulatory Filings for a product that such Party has a license or right to develop in a given country or jurisdiction;

(c) made by or on behalf of the Receiving Party as may be reasonably necessary for [**] as permitted by this Agreement;

(d) made by or on behalf of the Receiving Party for the purpose of complying with a valid order of a court of competent jurisdiction or other Governmental Authority of competent jurisdiction or, if in the opinion of the Receiving Party's legal counsel, such disclosure

is otherwise required by Applicable Law;

(e) made by or on behalf of the Receiving Party where such disclosure is required by a Regulatory Authority (including in filings with the Securities and Exchange Commission or other agency) of certain material developments or material information generated under this Agreement;

(f) made by or on behalf of the Receiving Party as of the Effective Date in response to a valid request by a U.S., state, foreign, provincial, or local tax authority, in which case either Party may disclose, a copy of this Agreement (including any Schedules, ancillary agreements, and amendments hereto);

(g) made by the Receiving Party to its and its Affiliates' employees, consultants, contractors and agents, and to Sublicensees (in the case of Lilly), in each case on a need-to-know basis (as reasonably determined by the Receiving Party) in connection with the Exploitation of Licensed Products or Terminated Products or Targets (if applicable) in the Field in the Territory, in each case under written obligations of confidentiality and non-use at least as stringent as those herein; and

(h) made to an investor, acquirer or merger partner *provided* that: (i) [**], (ii) [**], (iii) the Receiving Party shall be permitted to disclose only (x) [**] under this Agreement, and (y) [**]; *provided* that with respect to a [**] acquirer or merger partner, the Receiving Party may disclose to such potential acquirer or merger partner [**], and (iv) [**] in such group of prospective investors, acquirers or merger partners) is [**], then the terms of Section 18.8.2 shall apply.

If a Party is required to make a disclosure of the other Party's Confidential Proprietary Information pursuant to Section 14.1.4(c) or Section 14.1.4(d), it shall, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use efforts to secure confidential treatment of such Confidential Proprietary Information at least as diligent as such Party would use to protect its own Confidential Proprietary Information, but in no event less than reasonable efforts. Any information disclosed pursuant to this Section 14.1.4 remains Confidential Proprietary Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Article 14. Notwithstanding anything to the contrary set forth herein, no summary, abstract, compendium, survey, overview, notes or other report delivered by a Party pursuant to an obligation set forth under this Agreement, or otherwise shared between the Parties in connection with discussions of the JSC or its subcommittees, shall be disclosed by a Party to a Third Party without the prior written consent of the other Party.

14.2.Public Domain Information and Residual Knowledge. Nothing in this Agreement shall prevent a Party from using any information that is in the public domain. A Party shall also not be restricted under, and shall not be in breach of, this Agreement from using, within or outside this Agreement and for any purpose, any general knowledge, skill, and expertise acquired by its employees (or its Affiliates' employees) in their performance of this Agreement ("**Residuals**") solely to the extent such Residuals [**]; provided that this provision will not be deemed in any event to provide any right to infringe, or to grant any license to or under, the Intellectual Property Rights of the other Party or of Third Parties that have licensed or provided materials to the other Party; provided, further, that a Party's use of such Residuals is on an "as is, where is" basis, with all faults and all representations and warranties disclaimed and at such Party's

sole risk.

14.3.Disclosure of Agreement. Notwithstanding the foregoing, either Party or its Affiliates may disclose the relevant terms of this Agreement: (a) to the extent required or advisable to comply with the rules and regulations promulgated by the U.S. Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory, provided that such Party shall submit only a redacted form of this Agreement, which redacted form of this Agreement shall be provided to the other Party for review and comment and which comments shall be considered in good faith by the disclosing Party; (b) upon request from a Governmental Authority (such as a tax authority), provided the disclosing Party uses reasonable efforts to ensure the Governmental Authority maintains such terms as confidential; (c) to applicable licensors, to the extent necessary to comply with the terms of any Third Party license agreement, the rights under which are sublicensed to the other Party under this Agreement; and (d) to the extent necessary to perform obligations or exercise rights under this Agreement, to any sublicensee, collaborator or potential sublicensee or potential collaborator of such Party, provided that any sublicensee, collaborator or potential sublicensee or collaborator agree in writing to be bound by obligations of confidentiality and non-use no less protective of the Disclosing Party than those set forth in this Agreement.

14.4.Survival. Each Party's obligations under this Article 14 (other than Sections 14.2 and 14.6) shall apply during the Term and continue for [**] thereafter with respect to Confidential Proprietary Information, except for information which is a "trade secret," for which each Party's obligations under Section 14.1 shall remain in place as long as the applicable Confidential Proprietary Information retains its status as a trade secret. Section 14.2 shall apply during the Term and shall survive any expiration or termination of this Agreement.

14.5.Publicity. Neither Party shall issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party, not to be unreasonably withheld, conditioned, or delayed; *provided* however, that neither Party will be prevented from complying with any duty of disclosure it may have pursuant to Applicable Laws or pursuant to the rules of any recognized stock exchange or quotation system subject to the restrictions set forth in Sections 14.1.4 and 14.3. If either Party desires to issue a press release or other public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof, the issuing Party will provide the other Party with a copy of the proposed press release or public statement. The issuing Party shall provide [**] for the Receiving Party to provide any comments on such proposed press release or public statement. If the reviewing Party provides any comments, the Parties shall consult with one another on such proposed press release or public statement and work in good faith to prepare a mutually acceptable press release or public statement. Each Party may repeat any information relating to this Agreement that has already been publicly disclosed in accordance with this Section 14.5, provided such information continues as of such time to be accurate.

14.6.Publication. Lilly shall be entitled to issue scientific publications and make presentations with respect to the Licensed Products, and their testing in accordance with Lilly's internal guidelines [**] subject to this Section 14.6. Verve shall provide [**] for Lilly to review any scientific publications regarding Licensed Products [**].

ARTICLE 15

HSR FILINGS AND CLOSING

15.1.HSR Filings. If required by Applicable Laws, after the Execution Date, both Parties shall file the appropriate notices with respect to the transactions contemplated hereby as promptly as reasonably practicable with the United States Federal Trade Commission ("**FTC**") and Department of Justice ("**DOJ**") under the Hart Scott Rodino Antitrust Improvements Act of 1976, as amended ("**HSR Act**"). Each of the Parties shall promptly supply the other with any information that may reasonably be required in order to effectuate the filings under the HSR Act. Each of the Parties shall notify the other promptly upon receipt from the FTC or DOJ in connection with any filing made under the HSR Act and of any request for amendments or supplements to any such filings or of any substantive communications with, and any other substantive inquiries or requests for additional information from, the FTC and DOJ. Each Party shall comply promptly, in accordance with advice received from counsel, as appropriate, with any such inquiry or request, provided, however, that neither Party shall be required to consent

to the divestiture or other disposition of any of its assets or the assets of its Affiliates or to consent to any other structural or conduct remedy, and each Party and its Affiliates shall have no obligation to contest, administratively or in court, any ruling, order or other action of the FTC or DOJ or any Third Party with respect to the transactions contemplated by this Agreement. Each Party shall be responsible for paying its own costs and expenses (including legal and consultants' fees) incurred in connection with obtaining clearance of the transactions contemplated hereby from the FTC and the DOJ, except that Lilly will pay the filing fees incurred by both Parties in connection with the filings required pursuant to the HSR Act. In the event the Parties determine that HSR filings are required, the Effective Date shall not be deemed to have occurred and this Agreement (other than this Article 15) shall not be binding until the HSR Clearance Date. As used herein, the "**HSR Clearance Date**" means the earlier of: (a) the date on which the FTC or DOJ shall notify the Parties of early termination of the waiting period under the HSR Act; or (b) the date on which the applicable waiting period under the HSR Act, or any agreed extension thereof, expires. Notwithstanding any other provisions of this Agreement to the contrary, either Party may terminate this Agreement effective upon notice to the other Party if the HSR Clearance Date has not occurred on or before the date that is **[**]** after the Parties make their respective HSR filings.

15.2. Conduct Pending HSR Clearance Date. If the Parties determine that HSR filings are required, between the date of execution of this Agreement and the earlier of the Effective Date or the date of termination, each Party shall conduct its business with respect to the intellectual property rights granted hereunder in the ordinary course, and it will refrain from taking any action or omitting to take any action that would have the effect of restricting or impairing the rights to be granted to either Party hereunder or preventing either Party's ability to perform its obligations under this Agreement.

15.3. Updates to Representations and Warranties after Execution Date. Within **[**]** after the HSR Clearance Date, each Party shall deliver to the other Party a notice either (a) describing any exceptions to such Party's representations and warranties under Article 12, if any, as if such representations and warranties were made as of the Effective Date or (b) stating that no exceptions apply. If (x) either Party provides notice stating an exception to the representations and warranties under Section 12.1, then the other Party will have the right to terminate this Agreement upon written notice given within **[**]** after receipt of the exception notice, which termination will have immediate effect, or (y) Verve provides notice stating any exception to the representations

and warranties under Section 12.2.1, Section 12.2.2, Section 12.2.3(c), or Section 12.2.4 (solely with respect to a disclosure against the last sentence thereof), then Lilly will have the right to

terminate this Agreement upon written notice given within [**] after receipt of the exception notice, which termination will have immediate effect.

ARTICLE 16

TERM & TERMINATION

16.1.Term. This Agreement commences on the Effective Date and, unless terminated earlier as provided in this Article 16, shall continue on a Licensed Product-by-Licensed Product basis until the expiration of the last Royalty Term (with the Royalty Term for a Co-Funded Product being determined as if it were a Royalty Product) in the Territory for such Licensed Product (the “**Term**”). Upon expiration (but not earlier termination) of this Agreement, with respect to a given Licensed Product and a given country, the licenses granted by Verve to Lilly under Section 8.1 corresponding to such Licensed Product in such country shall continue in full force and effect and shall become fully paid, royalty-free, perpetual, and irrevocable and shall remain exclusive (even as to Verve and its Affiliates).

16.2.Termination for Material Breach.

16.2.1Termination. Either Party may terminate this Agreement upon written notice to the other Party if such other Party materially breaches its obligations under this Agreement and, after receiving written notice from the non-breaching Party identifying such material breach in reasonable detail, fails to cure such material breach within [**] from the date of such notice; *provided* that if such non-payment related breach is not reasonably capable of cure within such [**] period, the breaching Party may submit, prior to the end of such [**] period, a reasonable plan to cure the breach within an additional [**], in which case the other Party may not terminate this Agreement within such additional [**] so long as the breaching Party is using Commercially Reasonable Efforts to implement such cure plan during such period.

16.2.2Dispute. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 16.2.1, and such alleged breaching Party provides the other Party notice of such dispute within such [**] period, then the non-breaching Party may not terminate this Agreement under Section 16.2.1 unless and until it has been finally determined pursuant to Section 17.2 that the alleged breaching Party has materially breached this Agreement and such Party fails to cure such breach within [**] following such court’s or Executive Officer’s decision. During the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

16.2.3 Lilly Option to Continue. In the case where Lilly is entitled to terminate this Agreement in accordance with [**], Lilly may by written notice to Verve within [**] after the right to terminate arises, elect to reduce any amounts owed to Verve under Article 10 after the date giving rise to such right of termination by [**] percent ([**]%). Any such election must be in lieu of termination of the Agreement and will be Lilly's sole remedy for any such breach.

16.3.Termination by Lilly.

16.3.1 Partial Termination. Lilly may, at any time in its sole discretion and without cause, terminate this Agreement on a Research and Development Plan-by-Research and Development Plan, Licensed Target-by-Licensed Target or Licensed Product-by-Licensed Product basis upon ninety days (90) days' prior written notice to Verve.

16.3.2 Entire Agreement. Lilly may, in its sole discretion, terminate this Agreement in its entirety at any time and without cause upon one hundred eighty (180) days' prior written notice to Verve.

16.4.Termination for Cessation of Activity. "Cessation of Activity" means the occurrence of all of the following: [**]. In the event that the Parties agree Cessation of Activity has occurred (or, a final determination in accordance with Section 17.2 and 17.3 is made that Cessation of Activity has occurred), the relevant Licensed Target shall cease to be a Licensed Target under this Agreement, and any corresponding Licensed Products will be deemed Terminated Products (and, for the purposes of this Agreement, shall be deemed to have been terminated in accordance with Section 16.3.1) effective immediately upon [**].

16.5.Termination for Patent Challenge. Except to the extent the following is unenforceable under the Applicable Law of a particular jurisdiction where the applicable Licensed Patents are pending or issued, if (a) Lilly or any of its Affiliates or Sublicensees, without the prior written consent of Verve, voluntarily commences proceedings (whether before a regulatory or administrative body or a court) anywhere in the world, or requests that any Third Party commence, or voluntarily assists any Third Party in commencing or participating in, proceedings (whether before a regulatory or administrative body or a court) alleging that any claim in any such Licensed Patent is invalid, unenforceable, or otherwise not patentable, then (b) Verve will have the right to terminate this Agreement [**] on [**] written notice to Lilly, unless Lilly or its applicable Affiliate or Sublicensee withdraws (or causes to be withdrawn) such challenge within [**].

16.6.Effects of Termination. Upon any termination of this Agreement or, to the extent specified, upon expiration, the provisions of this Section 16.6 will apply, *provided* that if this

Agreement is terminated only with respect to specified Licensed Targets or Licensed Products and not in its entirety, then the following will apply to such Terminated Products or Targets only, and if this Agreement is terminated in its entirety, then all Licensed Targets or Licensed Products will be deemed Terminated Products or Targets.

16.6.1 Termination of Licenses. All licenses for Terminated Products or Targets granted by Verve under Article 8 (and if applicable, Lilly's license to Verve under Section 8.4) shall terminate automatically as of the effective date of termination; provided that, if Lilly (or its Affiliates or Sublicensees) has inventory of usable Licensed Product(s) as of the effective date of termination, then Lilly (and its Affiliates and Sublicensees) may continue to sell off such inventory of Licensed Products in the Field in the Territory (and fulfill customer orders therefor, including to Manufacture Licensed Products for customer orders placed prior to the effective date of termination) until the earlier to occur of [**] after the effective date of termination and the date on which Lilly (or its Affiliates or Sublicensees) no longer has such inventory of Licensed Product(s) and shall pay Verve any applicable payments due based on such sales. Any permitted sublicense granted by Lilly or its Affiliate to a Third Party under the licenses granted to Lilly under this Agreement shall survive the termination of this Agreement. If permitted under such surviving sublicense, effective upon termination of this Agreement, such sublicense shall become a direct license from Verve to such Sublicensee; provided that if assignment of the sublicense or such conversion of the sublicense to a direct license is not permitted under the applicable sublicense, Lilly shall be entitled to retain its right to payment thereunder and shall remain liable for royalties

under Section 10.4 of this Agreement with respect to sales by such Sublicensee. Notwithstanding the foregoing, after termination of this Agreement, Lilly and its Affiliates shall retain a non-exclusive, royalty-free, perpetual, sub-licensable right to use [**], for internal research and development purposes; provided, however, in no event will the foregoing right be construed as a right or license to Exploit any Verve Gene Editor, Verve Delivery Element, or the Verve Platform.

16.6.2 Destruction of Confidential Proprietary Information. Each Receiving Party shall destroy (at the Disclosing Party's written request) all such Confidential Proprietary Information of the Disclosing Party in its possession as of the effective date of expiration or termination (with the exception of one copy of such Confidential Proprietary Information, which may be retained by the legal department of the Receiving Party to confirm compliance with the non-use and non-disclosure provisions of this Agreement), and any Confidential Proprietary Information of the Disclosing Party contained in its laboratory notebooks or databases, provided that each Receiving Party may retain and continue to use such Confidential Proprietary Information of the

Disclosing Party to the extent necessary to exercise any surviving rights, licenses or obligations under this Agreement. [**].

16.6.3 *Reversion.*

(a) Following termination of this Agreement in its entirety or in part with respect to any Licensed Product, [**], to the extent requested by Verve in writing no later than [**] following the effective date of such termination (the “**Reversion Option**”), the Parties shall enter into an agreement (as described in (b) below) for Lilly to provide Verve, in exchange for commercially reasonable terms and consideration, (i) an exclusive, worldwide, sublicensable (through multiple tiers) right and license, in the Field and in the Territory, under the Lilly IP that Covers such Licensed Product, solely for use in connection with the Development, Manufacturing or Commercialization of such Licensed Product (*provided* that, in no event will Lilly be required to grant a license to its Background IP or any Manufacturing-related Intellectual Property Rights Controlled by Lilly), (ii) transfer and assignment to Verve of all Regulatory Approvals and Regulatory Documentation in the Territory solely related to such Licensed Product and a copy of all of the data comprising the global safety database for the Licensed Product; *provided* that if any Regulatory Approvals and Regulatory Documentation are necessary or useful for Exploitation of such Licensed Product and any other product, then Lilly will grant Verve a right of reference or use with respect to such approvals or documentation with respect to such Licensed Product in the Territory, (iii) transfer of Lilly’s inventory of such Licensed Product [**] to be agreed upon by the Parties, and (iv) Lilly’s performance of activities reasonably requested by Verve with respect to such Licensed Product to support an orderly transition thereof to Verve.

(b) Promptly after delivery of Verve’s notice that it is exercising the Reversion Option, the Parties will negotiate in good faith [**] (the “**Reversion Negotiation Period**”). [**].

16.6.4 *Refund of Cost-Sharing Fee and Development Costs.* If Verve has exercised the Cost-Sharing Option and this Agreement is terminated (i) by Lilly pursuant to Section 16.3 (except [**]) or (ii) by Verve pursuant to Section 16.2, in each case ((i) and (ii)), prior to Completion of a Phase 2 Clinical Trial for the applicable Co-Funded Product, then Lilly shall in the case of (i) and shall at Verve’s election in the case of (ii) pay Verve, within [**].

16.7.Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under the following

provisions of this Agreement shall survive expiration or termination of this Agreement: Article 1 (solely for purposes of interpreting other surviving provisions), Section 3.4 (solely to the extent of Lilly's obligation to pay [**] prior to the effective date of expiration or termination), Sections 8.1, 8.5 and 8.6 (solely with respect to the [**]), Section 8.2, Section 8.4.2, Section 8.7, Section 8.8, Article 10 ((i) excluding Section 10.2, (ii) solely to the extent relating to payment obligations accrued prior to the effective date of expiration or termination, and (iii) with respect to Section 10.12, for a period of [**] to permit Verve or Lilly to provide a final payment and report or conduct an audit if applicable), Sections 11.1 through 11.6 (inclusive), Section 11.7 (solely with respect to the payment obligations relating to Existing In-Licensed Technology and Future In-Licensed Technology that have accrued prior to the effective date of expiration or termination), Sections 11.8.1 and 11.8.2 (solely to the extent related to Prosecution and Maintenance of Joint Patents), Section 11.8.3 (first sentence only), Section 11.8.4 (excluding the first and last sentence, and solely to the extent related to Prosecution and Maintenance of Joint Patents, except that the Parties shall cooperate directly and not through the Patent Working Group), Section 11.13 (first sentence only), Section 11.14 (last sentence only), Section 13.1, Article 14 (solely as set forth in Section 14.4), Section 16.1 (last sentence only), Section 16.6, this Section 16.7, Article 17 and Article 18 (excluding Sections 18.7, 18.8, 18.14 and 18.18). Expiration or termination of this Agreement will not limit a Party's right to seek damages for a breach of this Agreement occurring prior to such expiration or termination.

16.8. Bankruptcy Code. If this Agreement is rejected or disclaimed by a Party as a debtor under Section 365 of the United States Bankruptcy Code or under any similar provisions in the bankruptcy, insolvency, reorganization or debtor relief laws of another jurisdiction (collectively, the "**Code**"), then, notwithstanding anything else in this Agreement to the contrary, all licenses and rights to licenses granted under or pursuant to this Agreement by the Party in bankruptcy to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Code (or similar provision in the bankruptcy laws of the jurisdiction), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code (or similar provision in the bankruptcy laws of another applicable jurisdiction). The Parties agree that a Party that is a licensee of rights under this Agreement shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against a Party under the Code, the other Party shall be entitled to a complete duplicate of, or complete access to (as such other Party deems appropriate), any such intellectual property and all embodiments of such intellectual property, if not already in such other Party's possession, shall be promptly delivered to such other Party: (a) upon any such commencement of a bankruptcy proceeding upon written request therefor by such other Party, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement; or (b) if not delivered under the foregoing subclause (a), upon the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party. The foregoing

provisions of this Section 16.8 are without prejudice to any rights a Party may have arising under the Code.

ARTICLE 17

GOVERNING LAW; DISPUTE RESOLUTION

17.1. Governing Law. This Agreement is governed by and will be construed in accordance with the laws of the State of New York, without reference to its conflict of laws principles. The United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention) does not apply to this Agreement.

17.2. Disputes. The Parties recognize that controversies or claims arising out of, relating to, or in connection with this Agreement may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties shall follow the procedures set forth in this Article 17 to resolve any dispute. If any dispute, claim or controversy of any nature arising out of or relating to this Agreement, including any action or claim based on tort, contract or statute, or concerning the interpretation, effect, termination, validity, performance or breach of this Agreement (each, a “**Dispute**”), arises between the Parties, either Party may refer the Dispute to the Executive Officers of each Party for resolution within [**] of a written request by either Party to the other Party (provided that no Dispute need be referred to Executive Officers for Escalation if the Executive Officers were already referred such matter pursuant to Section 7.6 as a result of a deadlock at the JSC). Each Party, within [**] after a Party has received such written request from the other Party to so refer such Dispute, shall notify the other Party in writing of the Executive Officer to whom such Dispute is referred, and such Executive Officers shall meet and seek to resolve such dispute in good faith (“**Escalation**”). If, after an additional [**] after the notice of Dispute, such Executive Officers taking part in such Escalation have not succeeded in negotiating a resolution of the Dispute, or the Dispute relates to a matter already referred to the Executive Officers pursuant to Section 7.6 without resolution within the time specified therein, and a Party wishes to pursue the matter further, such Party may seek to resolve the Dispute in any federal court having jurisdiction thereof located in New York, New York as further described in Section 17.3.

17.3. Litigation; Equitable Relief. The Federal courts located in New York, New York shall have exclusive jurisdiction over, and shall be the exclusive venue for resolution of, any Dispute not resolved through the informal dispute-resolution procedures described above. If, within [**] following a notice by either Party to the other that it does not believe the Dispute can be resolved through the Executive Officers, neither Party has commenced proceedings seeking to

resolve such Dispute in any federal court having jurisdiction, then such Dispute and all related rights, demands, claims, actions, causes of action, suits, proceedings and Losses of every kind and nature shall be deemed to have been irrevocably waived and released, to the fullest extent permitted under Applicable Laws. Either Party may, at any time and without waiving any remedy under this Agreement, seek from any court having jurisdiction any temporary injunctive or provisional relief necessary to protect the rights or property of that Party. Either Party may enforce any final judgment resolving a Dispute in any court having appropriate jurisdiction. Notwithstanding the foregoing, any challenge to a Patent (including, without limitation validity, enforceability, or otherwise) may be brought before the U.S. Patent and Trademark Office or similar foreign body.

ARTICLE 18

MISCELLANEOUS

18.1. Entire Agreement; Amendment. This Agreement, including the Schedules hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Execution Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof, including the Confidentiality Agreement. The foregoing may not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Execution Date, by the other Party of its obligations under the Confidentiality Agreement. No subsequent

alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

18.2. Limitation of Liability. Neither Party may recover from the other Party any special, incidental, consequential or punitive damages in connection with this Agreement, regardless of any notice of the possibility of such damages; *provided*, however, that this Section 18.2 shall not be construed to limit either party's indemnification obligations under Article 13, Verve's liability for breach of its exclusivity obligations under Article 9 or either Party's breach of its confidentiality obligations under Article 14 or liability of a party for its infringement or misappropriation of any Intellectual Property Rights or for a Party's gross negligence, willful misconduct or fraud.

18.3. Independent Contractors. The relationship between Lilly and Verve created by this Agreement is solely that of independent contractors. This Agreement does not create any

agency, distributorship, employee-employer, partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, nor can either Party assume or create any obligation, representation, warranty, or guarantee, express or implied, on behalf of the other Party.

18.4. Notice. Any notice required or permitted to be given by this Agreement must be in writing, in English. Any and all notices or other communications or deliveries required or permitted to be provided hereunder must be in writing and will be deemed given and effective if: (a) delivered by hand or by overnight courier with tracking capabilities; (b) mailed postage prepaid by first class, registered, or certified mail; or (c) delivered by electronic mail followed by delivery via either of the methods set forth in clauses (a) and (b) of this Section 18.4, in each case, addressed as set forth below unless changed by notice so given:

If to Verve:

Verve Therapeutics, Inc.
201 Brookline Avenue
Boston, MA 02215
Attn: Business Development
Email: [**]

With copies (which shall not constitute notice) to:

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
Attn: Sarah Tegan Hogan and Craig Hilts
Email: [**] and [**]

If to Lilly:

Eli Lilly and Company
Lilly Corporate Center

Indianapolis, Indiana 46285

Attn: [**]

With copies (which shall not constitute notice) to:

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
Attn: [**]

Attn: [**]

and

Weil, Gotshal & Manges LLP
767 Fifth Avenue
New York, NY 10153
Attn: Jeffrey D. Osterman, Esq.
E-mail: [**]

18.5. Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction: (a) such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement; (b) this Agreement shall be construed and enforced as if such invalid, unenforceable or illegal provision had never comprised a part hereof; and (c) all remaining portions will remain in full force and effect and shall not be affected by the invalid, unenforceable or illegal provision or by its severance herefrom.

18.6. Non-Use of Names. Verve shall not use the name, trademark, logo, or physical likeness of Lilly or its respective officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without Lilly's prior written consent. Verve shall require its Affiliates to comply with the foregoing. Lilly shall not use the name, trademark, logo, or physical likeness of Verve or its officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without Verve's prior written consent. Lilly shall require its Affiliates and Sublicensees to comply with the foregoing.

18.7. Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer without the other Party's consent to: (a) its Affiliate provided that such Party shall remain primarily liable for any acts or omissions of such Affiliate; or (b) to an Acquirer in connection with a Change of Control, subject to Section 18.8. Any permitted assignee shall, in writing to the non-assigning Party, expressly assume performance of such assigning Party's rights and obligations. Any permitted assignment is binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 18.7 is null, void and of no legal effect.

18.8. Verve Change of Control.

18.8.1 Notification of Change of Control. Verve shall provide Lilly with written notice of any Change of Control of Verve promptly, but no later than [**].

18.8.2 Acquirer Engaged in Competing Program or is a Lilly Competitor. [**].

18.8.3[**].

18.8.4[**].

18.8.5[**].

18.9. Waivers. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

18.10. Force Majeure. Neither Party shall be responsible to the other for any failure or delay in performing any of its obligations under this Agreement or for other nonperformance hereunder (excluding, in each case, the obligation to make payments when due) if such delay or nonperformance is caused by strike, fire, flood, earthquake, accident, war, act of terrorism, epidemics, pandemics, quarantines, act of God or of the government of any country or of any local government, or by any other cause unavoidable or beyond the control of any Party hereto. In such event, such affected Party shall use Commercially Reasonable Efforts to resume performance of its obligations and will keep the other Party informed of actions related thereto.

18.11. Interpretation. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Schedules mean the particular Articles, Sections or Schedules to this Agreement and references to this Agreement include all Schedules hereto. In the event of any conflict between the main body of this Agreement and any Schedule hereto, the main body of this Agreement shall apply. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation”; (b) the word “day” or “year” means a calendar day or year unless otherwise specified; (c) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (d) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words

appear; (e) the words “shall” and “will” have interchangeable meanings for purposes of this Agreement; (f) provisions that require that a Party, the Parties or a committee hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (g) words of any gender include the other gender; (h) words using the singular or plural number also include the plural or singular number, respectively; (i) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof; (j) the phrase “non-refundable” shall not prohibit, limit

or restrict either Party’s right to obtain damages in connection with a breach of this Agreement; (k) neither Party shall be deemed to be acting on behalf of the other Party; and (l) the word “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or”.

18.12. Counterparts; Electronic Signatures. This Agreement may be executed in any number of counterparts, each of which is deemed an original, but all of which together constitute one instrument. This Agreement may be executed and delivered electronically and upon such delivery such electronic signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

18.13. Expenses. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and execution of this Agreement.

18.14. Further Assurances. Lilly and Verve hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all documents and take any action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

18.15. No Third Party Beneficiary Rights. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

18.16. Construction. The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all

Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

18.17.Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

18.18.Extension to Affiliates. Except as expressly set forth otherwise in this Agreement, each Party shall have the right to extend the rights and immunities granted in this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement, except this right to extend, shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to the Party extending such rights and immunities. For clarity, Lilly extending the rights and immunities granted hereunder shall remain primarily liable for any acts or omissions of its Affiliates.

[Signature page follows.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Execution Date.

VERVE THERAPEUTICS, INC.

By: /s/ Andrew Ashe

Name: Andrew Ashe

Title: President and Chief Operating Officer

Date: June 13, 2023

[Signature Page to Research and Collaboration Agreement]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Execution Date.

ELI LILLY AND COMPANY

By: /s/ David A. Ricks

Name: David A. Ricks

Title: Chairman and Chief Executive
Officer

Date: June 14, 2023

[Signature Page to Research and Collaboration Agreement]

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.

STOCK PURCHASE AGREEMENT

This STOCK PURCHASE AGREEMENT (this “Agreement”) is made and entered into as of June 14, 2023, by and between Verve Therapeutics, Inc., a Delaware corporation (the “Company”), and Eli Lilly and Company, an Indiana corporation (the “Lilly”).

RECITALS

A. On the date hereof, the Company and Lilly entered into a Research and Collaboration Agreement (as defined below);

B. Lilly wishes to purchase from the Company, and the Company wishes to sell and issue to Lilly, upon the terms and subject to the conditions stated in this Agreement, shares of the Company’s common stock, par value \$0.001 per share (the “Common Stock”);

In consideration of the mutual promises made herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Definitions. For the purposes of this Agreement, the following terms shall have the meanings set forth below:

“Affiliate” means, with respect to any Person, any other Person which directly or indirectly through one or more intermediaries Controls, is controlled by, or is under common Control with such Person, for so long as such Control exists.

“Aggregate Purchase Price” has the meaning set forth in Section 2.

“Agreement” has the meaning set forth in the first paragraph.

“Applicable Laws” has the meaning set forth in Section 4.15.

“Authorizations” has the meaning set forth in Section 4.15.

“Business Day” means a day, other than a Saturday or Sunday, on which banks in New York City or Indianapolis, Indiana are open for the general transaction of business.

"Change of Control" with respect to the Company: (a) the acquisition by a Third Party, whether in one transaction or a series of related transactions, of direct or indirect beneficial ownership of more than fifty percent (50%) of the outstanding voting equity securities of the Company; (b) a merger, reorganization or consolidation involving the Company, as a result of which a Third Party acquires direct or indirect beneficial ownership of more than fifty percent (50%) of the voting power of the surviving entity immediately after such merger, reorganization or consolidation or the holders of the Company's outstanding voting securities immediately prior to the consummation of any such transaction (in their capacities as such) hold less than a majority of the outstanding voting securities of the surviving entity (or the parent company of such surviving entity, as applicable); or (c) a sale, exclusive license or other

transfer of all or substantially all of the assets of the Company in one transaction or a series of related transactions to a Third Party.

"Closing" has the meaning set forth in Section 3.1.

"Closing Date" has the meaning set forth in Section 3.1.

"Common Stock" has the meaning set forth in the recitals to this Agreement.

"Common Stock Equivalents" means any securities of the Company which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, rights, options, warrants or other instrument or securities that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Company" has the meaning set forth in the first paragraph.

"Company Data" has the meaning set forth in Section 4.17.

"Company's Knowledge" means the actual knowledge of the executive officers (as defined in Rule 405 under the 1933 Act) of the Company after due inquiry.

"Confidentiality Agreement" means that certain Confidentiality Agreement between Lilly and Verve, dated as of [**], as amended by Lilly and Verve pursuant to the First Amendment to the Confidentiality Agreement, dated as of [**].

"Control" (including the terms "controlling," "controlled by" or "under common control with") means to possess, directly or indirectly, the power to direct or cause the direction of the management or policies of an entity, whether through ownership of voting securities, by contract or otherwise.

"Data Protection Requirements" has the meaning set forth in Section 4.17.

"Disposition" or "Dispose of" means any (a) pledge, sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any shares of Common Stock, or any Common Stock Equivalents, including, without limitation, any "short sale" or similar arrangement, or (b) swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of shares of Common Stock, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.

"EDGAR system" has the meaning set forth in Section 4.8.

"Environmental Laws" has the meaning set forth in Section 4.18.

"FDA" has the meaning set forth in Section 4.15.

"Form 10-K" has the meaning set forth in Section 4.7(a).

"Form 10-Q" has the meaning set forth in Section 4.7(a).

"GAAP" has the meaning set forth in Section 4.7(b).

"HSR Act" has the meaning set forth in Section 7.2(b).

"Intellectual Property" has the meaning set forth in Section 4.13.

"IT Systems" has the meaning set forth in Section 4.17.

"LAS" means the Nasdaq Notification Form: Listing of Additional Shares.

"Lilly" has the meaning set forth in the first paragraph.

"Lilly Group" shall have the meaning set forth in Section 7.6.

"Lock-Up Securities" shall have the meaning set forth in Section 7.5(a).

"Lock-Up Term" means the period from and after the date of this Agreement until the date that is nine months after the Closing Date.

"Material Adverse Effect" means any change, event or occurrence that, individually or in the aggregate, results in, or would reasonably be expected to result in, a material adverse effect on (a) the assets, liabilities, results of operations, financial condition or business of the Company and its Subsidiary

taken as a whole, (b) the legality or enforceability of this Agreement or (c) the ability of the Company to perform its obligations under this Agreement.

"Material Contract" means any contract, instrument or other agreement to which the Company or its Subsidiary is a party or by which either is bound that is described in Item 601(b)(4) or Item 601(b)(10) of Regulation S-K.

"Nasdaq" means the Nasdaq Global Select Market.

"OFAC" has the meaning set forth in Section 4.28.

"Per Share Purchase Price" shall mean \$19.32, which amount is equal to a 15% premium to the volume weighted average per share price of the Common Stock on the Nasdaq for the thirty (30) Trading Days prior to the date of the Research and Collaboration Agreement.

"Permitted Transferee" means (a) an Affiliate of Lilly that is wholly owned, directly or indirectly, by Lilly, or (b) an Affiliate of Lilly (or any Affiliate of such Affiliate) that wholly owns, directly or indirectly, Lilly, or the acquiring Person in the case of an acquisition of Lilly; it being understood that for purposes of this definition "wholly owned" shall mean an Affiliate in which Lilly owns, or an Affiliate that owns, as applicable, directly or indirectly, at least ninety-nine percent (99%) of the outstanding capital stock of such Affiliate or Lilly, as applicable.

"Person" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the 1934 Act.

"Research and Collaboration Agreement" means the Research and Collaboration Agreement, dated as of June 14, 2023, between Lilly and the Company.

"SEC" means the U.S. Securities and Exchange Commission.

"SEC Filings" has the meaning set forth in Section 4.7.

"Shares" has the meaning set forth in Section 2 of this Agreement.

"Shares of Then Outstanding Common Stock" means, at any time, the issued and outstanding shares of Common Stock at such time, as well as all capital stock issued and outstanding as a result of any

stock split, stock dividend, or reclassification of Common Stock distributable, on a pro rata basis, to all holders of Common Stock.

"Subsidiary" has the meaning set forth in Section 4.1.

"Tax" or "Taxes" shall mean all federal, state, local, and foreign income, excise, gross receipts, gross income, ad valorem, profits, gains, property, capital, sales, transfer, use, payroll, employment, severance, withholding, duties, intangibles, franchise, backup withholding, value-added, and other taxes imposed by a governmental authority, together with all interest, penalties and additions to tax imposed with respect thereto.

"Tax Return" shall mean a report, return or other document (including any amendments thereto) required to be supplied to a governmental authority with respect to Taxes.

"Termination Date" has the meaning set forth in Section 8.1.

"Third Party" means any Person other than Lilly, the Company or any of their respective Affiliates.

"Trading Day" shall mean each day on which the Nasdaq is open for trading.

"Transfer Agent" has the meaning set forth in Section 7.3(a).

"1933 Act" means the Securities Act of 1933, as amended, or any successor statute, and the rules and regulations promulgated thereunder.

"1934 Act" means the Securities Exchange Act of 1934, as amended, or any successor statute, and the rules and regulations promulgated thereunder.

2. Purchase and Sale of the Shares. On the Closing Date, upon the terms and subject to the conditions set forth herein, the Company will issue and sell, and Lilly will purchase 1,552,795 shares (the "Shares") at the Per Share Purchase Price for an aggregate purchase price of \$29,999,999.40 (the "Aggregate Purchase Price").

3. Closing.

3.1 The completion of the purchase and sale of the Shares (the "Closing") shall occur remotely via exchange of documents and signatures on the third (3rd) Business Day following the date on which all conditions to closing set forth in Section 6 have been satisfied or waived, or such other place, time and date as may be agreed between the Company and Lilly (the "Closing Date").

3.2 On the Closing Date, Lilly shall deliver or cause to be delivered to the Company, via wire transfer of immediately available funds pursuant to the wire instructions delivered to Lilly by the

Company, the Aggregate Purchase Price. The Company shall notify Lilly in writing of such wire instructions not less than [**] prior to the Closing Date.

3.3 At or before the Closing, the Company shall deliver or cause to be delivered to Lilly the Shares, registered in the name of Lilly (or its nominee in accordance with its delivery instructions). The Shares shall be delivered to Lilly via a book-entry record through the Company's Transfer Agent (as defined below).

4. Representations and Warranties of the Company. The Company hereby represents and warrants to Lilly that, except as described in the Company's SEC Filings (as defined below) filed at least [**] prior to the date of this Agreement (excluding any disclosures set forth in such SEC Filings contained in any "Risk Factors" section or any "forward looking statements" or similar disclaimer or any other disclosure included in such SEC Filings that is predictive or forward-looking in nature), which qualify these representations and warranties in their entirety:

4.1 Organization, Good Standing and Qualification. The Company is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has all requisite corporate power and authority to carry on its business as now conducted and to own or lease and use its properties and assets. The Company is duly qualified to do business as a foreign corporation and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property makes such qualification or leasing necessary unless the failure to so qualify has not had and would not reasonably be expected to have a Material Adverse Effect. The Company's only subsidiary is set forth on Exhibit 21.1 to its most recent Annual Report on Form 10-K (the "Subsidiary"), and the Company owns 100% of the outstanding equity of such Subsidiary, and no Person has any rights pursuant to which the Company or its Subsidiary is or may become obligated to issue or sell any shares of capital stock or other securities of the Subsidiary. Other than such Subsidiary, each of the Company and the Subsidiary do not currently own or control, directly or indirectly, any interest in any other corporation, partnership, trust, joint venture, limited liability company, association, or other business entity. Neither the Company nor the Subsidiary is a participant in any material joint venture, partnership or similar arrangement. The Subsidiary is duly organized, validly existing and in good standing under the laws of the Commonwealth of Massachusetts and has all requisite power and authority to carry on its business as now conducted and to own or lease and use its properties and assets. True and correct copies of the Company's organizational documents are filed or incorporated by reference as exhibits to the Company's SEC Filings.

4.2 Authorization. The Company has the requisite corporate power and authority and has taken all requisite corporate action necessary for, and no further action on the part of the Company, its officers, directors and stockholders is necessary for, (a) the authorization, execution and delivery of this Agreement, (b) the authorization of the performance of all obligations of the Company and to carry out the other transactions contemplated hereunder, and (c) the authorization, issuance (or reservation for issuance) and delivery of the Shares. This Agreement has been duly executed and delivered by the Company, and upon the due execution and delivery of this Agreement by Lilly, will constitute the legal,

valid and binding obligations of the Company, enforceable against the Company in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability, relating to or affecting creditors' rights generally and to general equitable principles. No stop order or suspension of trading has been imposed by Nasdaq, the SEC or any other governmental or regulatory body with respect to public trading in the Common Stock.

4.3 Capitalization and Voting Rights.

(a) The Company is authorized under its Restated Certificate of Incorporation ("Certificate of Incorporation") to issue (i) 200,000,000 shares of Common Stock, of which, as of June

11, 2023, 62,001,113 shares are issued and outstanding and (ii) 5,000,000 shares of preferred stock, \$0.001 par value per share, none of which are issued and outstanding as of the date of this Agreement.

(b) The Company's disclosure of its issued and outstanding capital stock in its most recent SEC Filing containing such disclosure is accurate in all material respects as of the date hereof, except that options reflected as outstanding in such SEC Filing may have been exercised for shares of Common Stock, restricted stock units reflected in such SEC Filing may have vested and converted into shares of Common Stock, and shares of Common Stock issuable pursuant to the Company's employee stock purchase plan may have been issued since the date indicated in such SEC Filing.

(c) All of the issued and outstanding shares of the Company's capital stock have been duly authorized and validly issued and are fully paid and nonassessable; none of such shares were issued in violation of any preemptive rights; and such shares were issued in compliance in all material respects with applicable state and federal securities law and any rights of third parties.

(d) No Person is entitled to preemptive or similar statutory or contractual rights with respect to the issuance by the Company of any securities of the Company, including, without limitation, the Shares.

(e) Except for stock options and restricted stock units approved pursuant to Company stock-based compensation plans and employee stock purchase plans described in the SEC Filings, there are no outstanding equity securities, warrants, options, convertible securities or other rights, agreements or arrangements of any character under which the Company is or may be obligated to issue any equity securities of any kind, except as contemplated by this Agreement.

(f) There are no voting agreements, buy-sell agreements, option or right of first purchase agreements or other agreements of any kind among the Company and any of the securityholders of the Company relating to the securities of the Company held by them.

(g) The issuance and sale of the Shares hereunder will not obligate the Company to issue shares of Common Stock or other securities to any other Person (other than Lilly) and will not result in the adjustment of the exercise, conversion, exchange or reset price of any outstanding security.

(h) All of the authorized shares of Common Stock are entitled to one (1) vote per share.

(i) The Company does not have outstanding any stockholder rights plans or “poison pill” or any similar arrangement in effect giving any Person the right to purchase any equity interest in the Company upon the occurrence of certain events.

4.4 Valid Issuance. The Shares have been duly and validly authorized and, when issued and paid for pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and shall be free and clear of all encumbrances and restrictions (other than those created by Lilly), including preemptive rights, rights of first refusal or other similar rights of stockholders of the Company, except for restrictions on transfer set forth in this Agreement or imposed by applicable securities laws.

4.5 Consents. The execution, delivery and performance by the Company of this Agreement and the offer, issuance and sale of the Shares require no consent, approval, authorization or other order of, action by or in respect of, or filing with, any Person, governmental body, agency, or official other than (i) filings that have been made pursuant to applicable state securities laws, (ii) post-sale filings pursuant to

applicable state and federal securities laws and (iii) filings pursuant to the rules and regulations of Nasdaq, each of which the Company has filed or undertakes to file within the applicable time.

4.6 No Material Adverse Change. Since December 31, 2022, except as identified and described in the SEC Filings filed at least [**] prior to the date of this Agreement:

(a) there has not been any change in the consolidated assets, liabilities, financial condition or operating results of the Company from that reflected in the financial statements included in the Company’s Form 10-K (as defined below), except for changes in the ordinary course of business which are not and would not reasonably be expected to be material to the Company or its Subsidiary, taken as a whole;

(b) there has not been any declaration or payment by the Company of any dividend, or any authorization or payment by the Company of any distribution, on any of the capital stock of the Company, or any redemption, repurchase or other acquisition by the Company of any securities of the Company;

(c) the Company and its Subsidiary have not sold, transferred or otherwise disposed of any material assets or rights;

(d) there has not been any material damage, destruction or loss (whether or not covered by insurance) involving any material asset or right of the Company and its Subsidiary;

(e) there has not been any material obligation or liability incurred, any material loans or advances made, or any other material transactions entered into, by the Company or its Subsidiary to or with any of its or their other Affiliates, other than in the ordinary course of business;

- (f) any purchase or acquisition, or agreement, plan or arrangement to purchase or acquire, any material property, rights or assets, other than in the ordinary course of business by the Company or its Subsidiary;
- (g) any material waiver of any material rights or claims of the Company or its Subsidiary;
- (h) any material lien upon, or adversely affecting, any material property or other material assets of the Company or its Subsidiary;
- (i) any contract entered into by the Company or its Subsidiary to do any of the foregoing;
- (j) the Company has not admitted in writing its inability to pay its debts generally as they become due, filed or consented to the filing against it of a petition in bankruptcy or a petition to take advantage of any insolvency act, made an assignment for the benefit of creditors, consented to the appointment of a receiver for itself or for the whole or any substantial part of its property, or had a petition in bankruptcy filed against it, been adjudicated bankrupt or filed a petition or answer seeking reorganization or arrangement under the federal bankruptcy laws or any other laws of the United States or any other jurisdiction; and
- (k) there has not been any other event, change, development, occurrence, circumstance or condition that, individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect.

4.7 SEC Filings.

- (a) The Company has (i) timely filed all reports, schedules, forms, statements and other documents required to be filed with the SEC since January 1, 2022 (all of the foregoing and all exhibits included therein and financial statements and schedules thereto and documents (other than exhibits) incorporated by reference therein, collectively, the “SEC Filings”) and (ii) delivered or made available (by filing on the EDGAR system (as defined below)) to Lilly complete copies of the SEC Filings, including, but not limited to, its Annual Report on Form 10-K for the year ended December 31, 2022 (the “Form 10-K”) and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 (the “Form 10-Q”). As of its date, or if amended, as of the date of the last such amendment, each SEC Filing complied in all material respects with the requirements of the 1934 Act and the 1933 Act applicable to such SEC Filings, and, as of its date, or if amended, as of the date of the last such amendment, such SEC Filings did not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.
- (b) The consolidated financial statements of the Company included in the Form 10-K and Form 10-Q comply as to form in all material respects with the published rules and regulations of the SEC with respect thereto as in effect at the time of filing, have been prepared in accordance with generally accepted accounting principles in the United States (“GAAP”) applied on a consistent basis during the

periods involved (except as may be indicated in the notes thereto and except that the unaudited financial statements may not contain all footnotes required by GAAP, and, in the case of quarterly financial statements, except as permitted by Form 10-Q under the 1934 Act) and fairly present in all material respects the consolidated financial position of the Company as of the dates thereof and its consolidated results of its operations and cash flows for the periods then ended.

(c) The Company and its Subsidiary do not have any liabilities or obligations of any nature (whether accrued, absolute, contingent or otherwise), except for liabilities or obligations (a) reflected or reserved against on the most recent consolidated balance sheet of the Company included in the SEC Filings or the notes thereto, (b) incurred since the latest date of such balance sheet in the ordinary course of business or (c) that are not material to the Company and its Subsidiary, considered as a whole.

(d) As of the date of this Agreement, the Common Stock is listed on Nasdaq and registered pursuant to Section 12(b) of the 1934 Act, and the Company has taken no action designed to or reasonably likely to have the effect of terminating the registration of the Common Stock under the 1934 Act or delisting the Common Stock from Nasdaq. There are no proceedings pending or, to the Company's Knowledge, threatened against the Company relating to the continued listing of the Common Stock on Nasdaq. The Company is in compliance in all material respects with the requirements of Nasdaq for continued listing of the Common Stock thereon.

4.8 No Conflict, Breach, Violation or Default. The execution, delivery and performance of this Agreement by the Company and the issuance and sale of the Shares in accordance with the provisions thereof will not, except (solely in the case of clauses (a)(ii) and (b)) for such violations, conflicts or defaults as would not reasonably be expected, individually or in the aggregate, to have a material impact on the Company and its Subsidiary, considered as a whole, (a) conflict with or result in a breach or violation of (i) any of the terms and provisions of, or constitute a default under, the Company's Certificate

of Incorporation or the Company's Second Amended and Restated Bylaws (the "Bylaws"), both as in effect on the date hereof (true and complete copies of which have been made available to Lilly through the Electronic Data Gathering, Analysis, and Retrieval system (the "EDGAR system")), or (ii) assuming the accuracy of the representations and warranties in Section 5, any applicable statute, rule, regulation or order of any governmental agency or body or any court, domestic or foreign, having jurisdiction over the Company or its Subsidiary, or any of their assets or properties, or (b) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any lien, encumbrance or other adverse claim upon any of the Shares or any of the properties or assets of the Company or its Subsidiary or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any Material Contract.

4.9 Tax Matters. The Company and its Subsidiary have paid all income and other material Taxes, including federal, state, local and foreign Taxes, required to be paid by them. The Company and its Subsidiary have timely filed all income and other material Tax Returns required by law to be filed (taking into account any duly requested and applicable extensions thereof) and such Tax Returns are correct and

complete in all material respects; and there is no income or material Tax deficiency that has been, or could reasonably be expected to be, asserted against the Company or its Subsidiary or any of their respective properties or assets. There are no disputes pending, or claims asserted in writing, in respect of income or other material Taxes of the Company or its Subsidiary.

4.10 Title to Properties. The Company and its Subsidiary have good and marketable title to all real properties and all other properties and assets owned by them, in each case free from liens, encumbrances and defects, except such as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect; and the Company and its Subsidiary hold any leased real or personal property under valid and enforceable leases with no exceptions, except such as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

4.11 Certificates, Authorities and Permits. The Company and its Subsidiary possess all material certificates, authorities or permits issued by appropriate governmental agencies or bodies necessary to conduct the business now operated by them. The Company and its Subsidiary have not received any written notice of proceedings relating to the revocation or modification of any such certificate, authority or permit that would have a material impact on the Company and its Subsidiary, considered as a whole.

4.12 Labor Matters.

(a) The Company is not party to or bound by any collective bargaining agreements or other agreements with labor organizations. To the Company's Knowledge, the Company has not violated in any material respect any laws, regulations, orders or contract terms affecting the collective bargaining rights of employees or labor organizations, or any laws, regulations or orders affecting employment discrimination, equal opportunity employment, or employees' health, safety, welfare, wages and hours.

(b) No material labor dispute with the employees of the Company, or with the employees of any principal supplier, manufacturer, customer or contractor of the Company, exists or, to the Company's Knowledge, is threatened or imminent.

4.13 Intellectual Property. To the Company's Knowledge, the Company and its Subsidiary own or possess valid and enforceable licensed rights, or may acquire on reasonable terms sufficient to use, all material patents, patent applications, trademarks, service marks, trade names, Internet domain names, copyrights, proprietary information and know-how (including trade secrets and other unpatented

and/or unpatentable proprietary or confidential information, systems or procedures) as described in the SEC Filings (collectively, "**Intellectual Property**") necessary for the conduct of its business as currently conducted or as proposed to be conducted, and except where any failure to own, possess or acquire such Intellectual Property would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company-owned Intellectual Property has not been adjudged by a court of competent jurisdiction to be invalid or unenforceable, in whole or in part. There are no third parties who have rights to any Intellectual Property of the Company or its Subsidiary, except for customary reversionary rights of third-party licensors with respect to Intellectual Property that is disclosed in the SEC

Filings as licensed to the Company or its Subsidiary. To the Company's Knowledge there is no infringement by third parties of any Intellectual Property of the Company. Except as disclosed in the SEC Filings, there is no pending or existing threatened-in-writing action, suit or proceeding by others: (A) challenging the Company's or its Subsidiary's rights in or to any Intellectual Property of the Company; (B) challenging the validity, enforceability or scope of any Intellectual Property of the Company or its Subsidiary; or (C) asserting that the Company or its Subsidiary infringes, misappropriates or otherwise violates, or would, upon the commercialization of any product or service described in the SEC Filings as under development, infringe, misappropriate, or otherwise violate, any intellectual property rights of others. The Company has complied in all material respects with the terms of each agreement pursuant to which Intellectual Property of the Company has been licensed to the Company and its Subsidiary, and all such agreements are in full force and effect. To the Company's Knowledge, there are no material defects in any of the patents or patent applications included in the Company-owned Intellectual Property, that would render them unenforceable once issued. The patents included in the Intellectual Property of the Company are subsisting and have not lapsed and the patent applications in the Intellectual Property of the Company are subsisting and have not been abandoned. The Company has taken reasonable steps to protect, maintain and safeguard the Intellectual Property of the Company, including the execution of appropriate nondisclosure, confidentiality agreements and invention assignments with its employees.

4.14 Healthcare Regulatory Compliance. Each of the Company and its Subsidiary is, and at all times has been, in compliance in all material respects with all Health Care Laws to the extent applicable to the Company or its business. For purposes of this Agreement, "Health Care Laws" means: (i) the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and the regulations promulgated thereunder; (ii) all applicable federal, state, local and foreign health care fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the U.S. Civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal False Statements Law (42 U.S.C. Section 1320a-7b(a)), 18 U.S.C. Sections 286, 287 and 1349, the health care fraud criminal provisions under HIPAA (42 U.S.C. Section 1320d et seq.), the civil monetary penalties law (42 U.S.C. Section 1320a-7a), the exclusions law (42 U.S.C. Section 1320a-7), and laws governing government funded or sponsored healthcare programs; (iii) HIPAA, as amended by the HITECH Act (42 U.S.C. Section 17921 et seq.); (iv) the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010; (v) licensure, quality, safety and accreditation requirements under applicable federal, state, local or foreign laws or regulatory bodies; (vi) all other local, state, federal, national, supranational and foreign laws, relating to the regulation of the Company; and (vii) the directives and regulations promulgated pursuant to such statutes and any state or non-U.S. counterpart thereof. The Company, its Subsidiary and each of their officers, directors, employees and, to the knowledge of the Company, their agents have not engaged in activities which are, as applicable, cause for liability under a Health Care Law. Neither the Company nor its Subsidiary have received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in violation of any Health Care Laws nor, to the Company's Knowledge, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened. Each of the Company and its Subsidiary has filed, maintained or submitted all material

reports, documents, forms, notices, applications, records, claims, submissions, and supplements or amendments as required by any Health Care Laws, and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed in all material respects (or were corrected or supplemented by a subsequent submission). Neither the Company, its Subsidiary nor their employees, officers, directors, or, to the knowledge of the Company, their agents is a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental or regulatory authority related to activities conducted by or on behalf of the Company or its Subsidiary. Additionally, neither the Company, its Subsidiary nor their employees, officers, directors, or, to the knowledge of the Company, their agents has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

4.15 FDA Compliance. Each of the Company and its Subsidiary: (A) is and at all times has been in material compliance with all statutes, rules or regulations of the United States Food and Drug Administration (the “FDA”) and other comparable governmental entities with jurisdiction over the Company or its Subsidiary that are applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product under development, manufactured or distributed by the Company or its Subsidiary (“Applicable Laws”); (B) has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other written correspondence or notice from the FDA or any governmental entity alleging or asserting material noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, exemptions, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws (“Authorizations”); (C) possesses all material Authorizations and such Authorizations are valid and in full force and effect and the Company and its Subsidiary are not in material violation of any term of any such Authorizations; (D) has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the FDA or any governmental entity or third party alleging that any product operation or activity is in material violation of any Applicable Laws or Authorizations and has no knowledge that the FDA or any governmental entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (E) has not received written notice that the FDA or any governmental entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any material Authorizations and has no knowledge that the FDA or any governmental entity is considering such action; and (F) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were corrected or supplemented by a subsequent submission).

4.16 Tests and Preclinical and Clinical Trials. The studies, tests and preclinical and clinical trials conducted by or, to the Company's Knowledge, on behalf of the Company or its Subsidiary were and, if still ongoing, are being conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to accepted professional scientific standards and all applicable Authorizations and Applicable Laws, including, without limitation, the Federal Food, Drug and Cosmetic Act and the rules and regulations promulgated thereunder and current Good Clinical Practices and Good Laboratory Practices and any applicable rules, regulations and policies of the jurisdiction in which such trials and studies are being conducted; and, except to the extent disclosed in SEC Filings, the Company and its Subsidiary have not received any notices or correspondence from the FDA or any governmental entity requiring the termination or suspension of any studies, tests or

preclinical or clinical trials conducted by or on behalf of the Company or its Subsidiary, other than ordinary course communications with respect to modifications in connection with the design and implementation of such trials.

4.17 Cybersecurity; Data Protection. The Company's information technology assets and equipment, including, without limitation, those owned, licensed or otherwise used (excluding any public networks), such as its data communications lines, computers, systems, networks, hardware, servers, software, websites, applications, and databases (collectively, "IT Systems") are adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company as currently conducted and as proposed to be conducted as described in the Registration Statement and the Prospectus, free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company has at all times implemented and maintained reasonable and appropriate controls, policies, procedures, and safeguards consistent with industry standards and practices for similarly situated companies to maintain and protect the integrity, availability, privacy, continuous operation, redundancy and security of all IT Systems and data (including all sensitive, confidential or regulated data and all data that comes within a definition of "personal information," "personal data" or other similar term under Data Protection Requirements) (collectively, "Company Data") used in connection with their business, and there have been no breaches, violations, outages, compromises, or unlawful or unauthorized acquisitions of, disclosures of, uses of or accesses to the same, except in each case as would not, individually or in the aggregate, reasonably be expected to have a material impact on the Company and its Subsidiary, considered as a whole. There are no privacy or security incidents under internal review or investigations relating to the same that would, individually or in the aggregate, reasonably be expected to have a material impact on the Company and its Subsidiary, considered as a whole. Except in each case as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, the Company is presently and, at all times, has been in compliance with all (i) applicable laws, statutes, judgments, orders, rules and regulations of any court, arbitrator, governmental or regulatory authority; and (ii) internal policies and contractual obligations, each (i) and (ii) relating to the privacy and security of IT Systems and Company Data ("Data Protection Requirements").

4.18 Environmental Matters. The Company is not in violation of any statute, rule, regulation, decision or order of any governmental agency or body or any court, domestic or foreign, relating to the use, disposal or release of hazardous or toxic substances or relating to the protection or restoration of the environment or human exposure to hazardous or toxic substances (collectively, “Environmental Laws”), has not released any hazardous substances regulated by Environmental Law onto any real property that it owns or operates, and has not received any written notice or claim it is liable for any off-site disposal or contamination pursuant to any Environmental Laws, which violation, release, notice, claim, or liability would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, and to the Company’s Knowledge, there is no pending or threatened investigation that would reasonably be expected to lead to such a claim.

4.19 Legal Proceedings. There are no legal, governmental or regulatory investigations, actions, suits or proceedings pending, or to the Company’s Knowledge, threatened, to which the Company or its Subsidiary are or may reasonably be expected to become a party or to which any property of the Company or its Subsidiary are or may reasonably be expected to become the subject that, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect.

4.20 Insurance Coverage. The Company and its Subsidiary have insurance covering their respective properties, operations, personnel and businesses, including business interruption insurance, which insurance is in amounts and insures against such losses and risks as the Company reasonably

believes are prudent, customary and adequate to protect the Company and its Subsidiary and their respective businesses; and neither the Company nor its Subsidiary has (i) received notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance or (ii) any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage at reasonable cost from similar insurers as may be necessary to continue its business in all material respects.

4.21 Brokers and Finders. No Person will have, as a result of the transactions contemplated by this Agreement, any valid right, interest or claim against or upon the Company or Lilly for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of the Company.

4.22 No General Solicitation. Neither the Company nor any Person acting on its behalf has conducted any general solicitation or general advertising (as those terms are used in Regulation D promulgated under the 1933 Act) in connection with the offer or sale of any of the Shares.

4.23 No Integrated Offering. Neither the Company nor its Subsidiary nor any Person acting on their behalf has, directly or indirectly, made any offers or sales of any Company security or solicited any offers to buy any Company security, under circumstances that would require registration of the Shares under the 1933 Act.

4.24 Private Placement. Assuming the accuracy of the representations and warranties of Lilly set forth in Section 5, the offer and sale of the Shares to Lilly as contemplated hereby is exempt from the registration requirements of the 1933 Act and the registration and qualification requirements of all applicable securities laws of the states of the United States. The issuance and sale of the Shares does not contravene the rules and regulations of Nasdaq.

4.25 Internal Controls. The Company has established and maintains a system of “disclosure controls and procedures” (as defined in Rules 13a-15 and 15d-15 under the 1934 Act), which (a) complies with the requirements of the 1934 Act, (b) has been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the 1934 Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company’s management as appropriate to allow timely decisions regarding required disclosure, and (c) has been designed by the Company’s principal executive officer and principal financial officer, or under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Based on the Company’s most recent evaluation of its internal controls over financial reporting pursuant to Rule 13a-15 of the Exchange Act, there are no material weaknesses in the Company’s internal controls over financial reporting. Since the end of the Company’s most recent audited fiscal year, there have been (a) no material weaknesses in the Company’s internal control over financial reporting (whether or not remediated) and (b) no change in the Company’s internal control over financial reporting that has materially affected, or would reasonably be expected to materially affect, the Company’s internal control over financial reporting. The Company is not aware of any change in its internal controls over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or would reasonably be expected to materially affect, the Company’s internal control over financial reporting.

4.26 Investment Company. The Company is not required to be registered as, and is not an Affiliate of, and immediately following the Closing will not be required to register as, an “investment company” within the meaning of the Investment Company Act of 1940, as amended.

4.27 Anti-Bribery and Anti-Money Laundering Laws. Each of the Company, its Subsidiary and any of their respective officers, directors, supervisors, managers or employees, and to the Company’s Knowledge, agents are and have at all times been in compliance with, and its participation in the offering will not violate: (a) the applicable anti-bribery laws of all jurisdictions where the Company or its Subsidiary conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines issued, administered or enforced by any governmental agency, including but not limited to, any applicable law, rule, or regulation of any locality, including but not limited to any law, rule, or regulation promulgated to implement the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions; the U.S. Foreign Corrupt Practices Act of 1977, as amended; the U.K. Bribery Act 2010, or (b) the applicable financial recordkeeping and reporting requirements of Currency and Foreign Transactions Reporting Act of 1970, as amended, and the

applicable money laundering laws of all jurisdictions where the Company or its Subsidiary conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines issued, administered or enforced by any governmental agency. The Company and its Subsidiary have implemented and maintain in effect policies and procedures designed to promote compliance with applicable anti-bribery laws, rules, and regulations.

4.28 OFAC. Neither the Company, its Subsidiary nor any director, officer, employee, or, to the Company's Knowledge, agent or other person acting on behalf of the Company or its Subsidiary are currently the target of any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC") or have violated any such sanctions; and the Company will not directly or knowingly indirectly use the proceeds from the sale of the Shares, or lend, contribute or otherwise make available such proceeds to its Subsidiary or any joint venture partner or other person, for the purpose of financing the activities of or business with any person that currently is subject to any U.S. sanctions administered by OFAC, in any country or territory that is subject to comprehensive U.S. sanctions administered by OFAC, or in any other manner that will result in a violation by the Company or its Subsidiary of U.S. sanctions administered by OFAC.

4.29 Material Contracts. Each Material Contract is included as an exhibit in the SEC Filings. Each Material Contract is the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except in each case to the extent that (a) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general principles of equity that restrict the availability of equitable remedies and (b) the indemnification provisions of certain agreements may be limited by federal or state securities laws or public policy considerations in respect thereof. There has not occurred any material breach, violation or default by the Company under any such Material Contract or, to the Company's Knowledge, by any other Person to any such Material Contract. The Company has not been notified that any third party to any Material Contract has indicated that such third party intends to cancel, terminate or not renew any Material Contract.

5. Representations and Warranties of Lilly. Lilly hereby represents and warrants to the Company that:

5.1 Organization and Existence. Lilly is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has all requisite corporate power

and authority to enter into and consummate the transactions contemplated by this Agreement and to carry out its obligations hereunder and thereunder, and to invest in the Shares pursuant to this Agreement.

5.2 Authorization. The execution, delivery and performance by Lilly of this Agreement have been duly authorized and each has been duly executed and when delivered will constitute the valid and legally binding obligation of Lilly, enforceable against Lilly in accordance with their respective terms, subject to

bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability, relating to or affecting creditors' rights generally, and general principles of equity.

5.3Purchase Entirely for Own Account. The Shares to be received by Lilly hereunder will be acquired for Lilly's own account, not as nominee or agent, for the purpose of investment and not with a view to the resale or distribution of any part thereof in violation of the 1933 Act, and Lilly has no present intention of selling, granting any participation in, or otherwise distributing the same in violation of the 1933 Act without prejudice, however, to Lilly's right at all times to sell or otherwise dispose of all or any part of the Shares in compliance with applicable federal and state securities laws. The Shares are being purchased by Lilly in the ordinary course of its business. Lilly is not a broker-dealer registered with the SEC under the 1934 Act or an entity engaged in a business that would require it to be so registered.

5.4Investment Experience. Lilly acknowledges that it can bear the economic risk and complete loss of its investment in the Shares and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment contemplated hereby.

5.5Disclosure of Information. Lilly has had an opportunity to receive, review and understand information related to the Company requested by it and to ask questions of and receive answers from the Company regarding the Company, its business and the terms and conditions of the offering of the Shares, and has conducted and completed its own independent due diligence. Lilly acknowledges that copies of the SEC Filings are available on the EDGAR system. Based on the information Lilly has deemed appropriate, it has independently made its own analysis and decision to enter into this Agreement. Lilly is relying exclusively on the representations and warranties made by the Company in Section 4 hereof and its own investment analysis and due diligence (including professional advice it deems appropriate) with respect to the execution, delivery and performance of this Agreement, the Shares and the business, condition (financial and otherwise), management, operations, properties and prospects of the Company, including but not limited to all business, legal, regulatory, accounting, credit and tax matters. No inquiries nor any other investigation conducted by or on behalf of Lilly or its representatives or counsel will modify, amend or affect Lilly's right to rely on the Company's representations and warranties contained in this Agreement.

5.6Restricted Securities. Lilly understands that the Shares are characterized as "restricted securities" under the U.S. federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the 1933 Act only in certain limited circumstances. Lilly represents that it is familiar with Rule 144 as presently in effect.

5.7Legends. It is understood that, except as provided below, certificates evidencing the Shares (or uncertificated interests in the Shares) may bear the following or any similar legend:

(a) "The securities have not been registered with the Securities and Exchange Commission. They may not be sold, offered for sale, pledged or hypothecated in the absence of a

registration statement in effect with respect to the securities under the Securities Act of 1933 or an opinion of counsel (which counsel shall be reasonably satisfactory to Verve Therapeutics, Inc.) that such registration is not required or unless sold pursuant to Rule 144 of the Securities Act of 1933.”

(b) These securities are subject to transfer restrictions set forth in a Stock Purchase Agreement by and between Verve Therapeutics, Inc. and Eli Lilly and Company, a copy of which is on file with the Secretary of Verve Therapeutics, Inc.

5.8 Accredited Investor. Lilly is (a) an “accredited investor” within the meaning of Rule 501(a) of Regulation D and (b) an “Institutional Account” as defined in FINRA Rule 4512(c). Lilly is a sophisticated institutional investor with sufficient knowledge and experience financial and business matters that it is capable of evaluating the risks and merits of its purchase of the Shares.

5.9 Brokers and Finders. No Person will have, as a result of the transactions contemplated by this Agreement, any valid right, interest or claim against or upon the Company or Lilly for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of Lilly.

5.10 Beneficial Ownership. Other than with respect to the Shares, Lilly does not beneficially own any Common Stock, including any securities convertible into or exchangeable for Common Stock (including any such securities that cannot be converted or exchanged for more than 60 days from the date hereof). Excluded from the representation and warranty made in the previous sentence are any Common Stock or securities convertible into or exchangeable for Common Stock that may be owned of record or beneficially by any investment fund with respect to which Lilly does not direct its investment activities or any pension or other employee benefit plan administrator for any pension or other employee benefit plan maintained for the employees of Lilly or its Affiliates.

5.11 No Conflicts. The execution, delivery and performance by Lilly of this Agreement and the consummation by Lilly of the transactions contemplated hereby and thereby will not (i) result in a violation of the organizational documents of Lilly or (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which Lilly is a party, or (iii) result in a violation of any law, rule, regulation, order, judgment or decree (including federal and state securities laws) applicable to Lilly, except in the case of clauses (ii) and (iii) above, for such conflicts, defaults, rights or violations which would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the ability of Lilly to perform its obligations hereunder.

6. Conditions to Closing.

6.1 Conditions to Lilly’s Obligations. The obligation of Lilly to purchase Shares at the Closing is subject to the fulfillment to Lilly’s satisfaction, on or prior to the Closing Date, of the following conditions, any of which may be waived by Lilly:

(a) The representations and warranties made by the Company in Section 4 hereof shall be true and correct as of the date hereof and as of the Closing Date, as though made on and as of such date (except to the extent any such representation or warranty expressly speaks as of an earlier date, in which case such representation or warranty shall be true and correct as of such earlier date), except in each case where the failure of such representations and warranties to be so true and correct (without giving effect to

any limitation as to "Material Adverse Effect", "in all material respects", "material impact", "material" or "materiality" set forth therein) would not reasonably be expected to have a Material Adverse Effect.

(b) The Company shall have performed in all material respects all obligations and covenants herein required to be performed by it on or prior to the Closing Date.

(c) The Company shall have delivered a Certificate, executed on behalf of the Company by its Chief Executive Officer or its Chief Financial Officer, dated as of the Closing Date, certifying to the fulfillment of the conditions specified in Sections 6.1(a), (b) and (e).

(d) The Company shall have delivered a Certificate, executed on behalf of the Company by its Secretary, dated as of the Closing Date, certifying the resolutions adopted by the Board of Directors of the Company approving the transactions contemplated by this Agreement and the issuance of the Shares, certifying the current versions of the Certificate of Incorporation and Bylaws of the Company and certifying as to the signatures and authority of persons signing this Agreement and related documents on behalf of the Company.

(e) There shall have been no Material Adverse Effect with respect to the Company since the date hereof.

(f) No stop order or suspension of trading shall have been imposed or threatened in writing by Nasdaq, the SEC or any other governmental or regulatory body with respect to public trading in the Common Stock.

(g) The Company shall have executed and delivered Research and Collaboration Agreement and it shall be in full force and effect.

(h) All registrations, qualifications, permits and approvals, if any, required to be obtained prior to the Closing under applicable state securities laws shall have been obtained for the lawful execution, delivery and performance of this Agreement, including, without limitation, the offer and sale of the Shares.

(i) The filings required under the HSR Act in connection with this Agreement, as applicable, shall have been made and any applicable waiting period shall have expired or been terminated as of the Closing Date.

(j) The Company shall have taken all actions that are necessary, including providing appropriate notice to Nasdaq of the transactions contemplated by this Agreement, for the Shares purchased at the Closing to remain listed on Nasdaq and shall have complied with all listing, reporting, filing and other obligations under the rules of Nasdaq and of the SEC.

(k) No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or delay the Closing, will have been instituted or be pending before any court, arbitrator, governmental body, agency or official.

(l) The Company will have delivered to its transfer agent irrevocable written instructions to issue the Shares to Lilly in a form and substance acceptable to such transfer agent.

6.2 Conditions to Obligations of the Company. The Company's obligation to sell and issue Shares at the Closing is subject to the fulfillment to the satisfaction of the Company on or prior to the Closing Date of the following conditions, any of which may be waived by the Company:

(a) The representations and warranties made by Lilly in Section 5 hereof shall be true and correct as of the date hereof, and shall be true and correct as of the Closing Date with the same force and effect as if they had been made on and as of such date, except in each case where the failure of such representations and warranties to be so true and correct (without giving effect to any limitation as to "materiality" set forth therein) would not reasonably be expected to have a material adverse effect on Lilly's ability to perform its obligations hereunder or consummate the transactions contemplated hereby.

(b) Lilly shall have performed in all material respects all obligations and covenants herein required to be performed by it on or prior to the Closing Date.

(c) Lilly shall have paid in full the Aggregate Purchase Price to the Company.

(d) No stop order or suspension of trading shall have been imposed or threatened in writing by Nasdaq, the SEC or any other governmental or regulatory body with respect to public trading in the Common Stock.

(e) Lilly shall have executed and delivered the Research and Collaboration Agreement and it shall be in full force and effect.

(f) All registrations, qualifications, permits and approvals, if any, required to be obtained prior to the Closing under applicable state securities laws shall have been obtained for the lawful execution, delivery and performance of this Agreement, including, without limitation, the offer and sale of the Shares.

(g) The filings required under the HSR Act in connection with this Agreement, as applicable, shall have been made and any applicable waiting period shall have expired or been terminated as of the Closing Date.

(h) No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or delay the Closing, will have been instituted or be pending before any court, arbitrator, governmental body, agency or official.

7. Covenants and Agreements of the Parties.

7.1 Information Rights.

(a) During the Research Term (as defined in the Research and Collaboration Agreement), and as long as Lilly holds Common Stock of the Company equal to **[**]**% of the Shares, following regularly scheduled meetings of the Company's Board of Directors, Lilly shall have the right to consult with the Company's **[**]**, who shall make himself or herself reasonably available for such consultation, but who, for clarity, shall have no obligation pursuant to this Section 7.1(a) to disclose any confidential information of the Company or any Third Party to Lilly.

(b) Without limiting any other obligations of confidentiality that Lilly has to the Company under the Research and Collaboration Agreement and the Confidentiality Agreement, Lilly agrees that it will keep confidential any confidential information obtained from the Company, unless such confidential information is known or becomes generally known to the public in general (other than as a result of a breach of this Agreement or the Research and Collaboration Agreement). In addition, Lilly understands and acknowledges that the securities laws of the United States restrict any person who has

material, non-public information about a company from purchasing or selling any securities of such company while in possession of such information.

7.2 Market Listing; HSR Clearance.

(a) The Company shall use reasonable efforts to effect the listing of the Shares on Nasdaq, including submitting the LAS to the Nasdaq Stock Market, if required by the Nasdaq Stock Market.

(b) The Parties agree that any required filings with the United States Federal Trade Commission and Department of Justice under the Hart Scott Rodino Antitrust Improvements Act of 1976, as amended (the "**HSR Act**"), with respect to the transactions contemplated hereby and by the Research and Collaboration Agreement shall be governed by Article 15 of the Research and Collaboration Agreement.

7.3 Removal of Legends and Facilitation of Sales Pursuant to Rule 144.

(a) In connection with any sale, assignment, transfer or other disposition of the Shares by Lilly pursuant to Rule 144 or pursuant to any other exemption under the 1933 Act such that the purchaser acquires freely tradable shares and upon compliance by Lilly with the requirements of this Agreement, if requested by Lilly, the Company shall cause the transfer agent for the Common Stock (the "**Transfer Agent**") to remove any restrictive legends related to the book entry account holding such Shares

and make a new, unlegended entry for such book entry Shares sold or disposed of without restrictive legends within [**] of any such request therefor from Lilly, provided that the Company has timely received from Lilly customary representations and other documentation reasonably acceptable to the Company in connection therewith.

(b) Subject to receipt from Lilly by the Company and the Transfer Agent of customary representations and other documentation reasonably acceptable to the Company and the Transfer Agent in connection therewith, upon the earliest of such time as the Shares (i) have been sold pursuant to Rule 144 or (ii) are eligible for resale under Rule 144(b)(1) or any successor, the Company shall, in accordance with the provisions of this Section 7.3(b) and within [**] of any request therefor from Lilly accompanied by such customary and reasonably acceptable documentation referred to above, (A) deliver to the Transfer Agent irrevocable instructions that the Transfer Agent shall make a new, unlegended entry for such book entry Shares, and (B) cause its counsel to deliver to the Transfer Agent one or more opinions to the effect that the removal of such legends in such circumstances may be effected under the 1933 Act if required by the Transfer Agent to effect the removal of the legend in accordance with the provisions of this Agreement. Shares subject to legend removal hereunder may be transmitted by the Transfer Agent to Lilly by crediting the account of Lilly's broker with the DTC System as directed by Lilly. The Company shall be responsible for the fees of its Transfer Agent and all DTC fees associated with such issuance.

(c) The Company acknowledges and agrees that the combination of Lilly's purchase of the Shares pursuant to this Agreement and its rights pursuant to the Research and Collaboration Agreement, assuming no further acquisitions of Shares by Lilly or any Affiliates of Lilly or other changes to the relationship of the parties hereto, do not result in Lilly's being an affiliate of the Company for purposes of Rule 144. Subject to the accuracy of the representations and warranties made by Lilly in Section 5, other than the restrictive legends referred to in Section 5.7 hereof, the Company may not place any other legends on the Shares.

7.4 Confidentiality After the Date Hereof. Lilly covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company, Lilly will maintain the confidentiality of all disclosures made to it in connection with such transactions (including the existence and terms of this transaction), other than to such Person's outside attorney, accountant, auditor or investment advisor only to the extent necessary to permit evaluation of the investment, and the performance of the necessary or required Tax, accounting, financial, legal, or administrative tasks and services and other than as may be required by law.

7.5 Restrictions on Dispositions.

(a) **Lock-Up.** During the Lock-Up Term, without the prior approval of the Company, Lilly shall not, and shall cause its Affiliates not to, Dispose of (x) any of the Shares, together with any shares of Common Stock issued in respect thereof as a result of any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization, and (y) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with

respect to, or in exchange or in replacement of, the shares of Common Stock described in clause (x) of this sentence (collectively, the “Lock-Up Securities”), including, without limitation, any “short sale” or similar arrangement; provided, however, that the foregoing shall not prohibit Lilly from transferring Lock-Up Securities to a Permitted Transferee.

(b) Certain Tender Offers and Dispositions. This Section 7.5 shall not prohibit or restrict any Disposition of Shares of Then Outstanding Common Stock and/or Common Stock Equivalents (i) into a tender or exchange offer by a Third Party for shares of the Common Stock or (ii) into an issuer tender offer by the Company.

(c) Termination of Lock-Up. This Section 7.5 shall terminate and have no further force or effect, upon the earliest to occur of: (i) the end of the Lock-up Term; (ii) the entry by the Company into a definitive agreement providing for a Change of Control or the consummation of a Change of Control; (iii) a liquidation or dissolution of the Company; and (iv) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the 1934 Act.

(d) Effect of Termination. No termination pursuant to Section 7.5(c) shall relieve any of the parties (or the Permitted Transferee, if any) for liability for breach of or default under any of their respective obligations or restrictions under any terminated provision of this Agreement, which breach or default arose out of events or circumstances occurring or existing prior to the date of such termination.

7.6 Right to Conduct Activities. The Company hereby agrees and acknowledges that Lilly is a public company with numerous business lines and an active investment and acquisition program. The Company hereby agrees that none of Lilly or any of its Affiliates (together, the “Lilly Group”) shall be liable to the Company or any of its Affiliates for any claim arising out of, or based upon, (a) the investment by the Lilly Group in any entity competitive with the Company, (b) actions taken by any partner, officer or other representative of the Lilly Group to assist any such competitive company, whether or not such action was taken as a member of the board of directors of such competitive company or otherwise, and whether or not such action has a detrimental effect on the Company, or (c) with respect to the Lilly Group, the Lilly Group’s engaging in any business; provided, however, that the foregoing shall not limit any of Lilly’s or any of its Affiliates’ obligations under the Research and Collaboration Agreement or otherwise relieve Lilly or any Affiliate of Lilly from liability associated with the breach by Lilly of any representation, warrant, covenant, agreement or obligation set forth in this Agreement or the Research and Collaboration Agreement, including (for the avoidance of doubt) Lilly’s obligations of

confidentiality and non-use under this Agreement, the Confidentiality Agreement and the Research and Collaboration Agreement.

8. Termination.

8.1 Ability to Terminate. This Agreement may be terminated at any time prior to the Closing by:

(a) mutual written consent of the Company and Lilly;

(b) either the Company or Lilly, upon written notice to the other after one hundred and eighty (180) days from the date of this Agreement (the "Termination Date"), if the transactions contemplated hereby have not been consummated by the Termination Date; provided, however, that the right to terminate this Agreement under this Section 8.1(b) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Termination Date;

(c) Lilly, if (i) any of the representations and warranties of the Company contained in Section 4 of this Agreement shall fail to be true and correct or (ii) there shall be a breach by the Company of any covenant of the Company in this Agreement that, in either case, (A) would result in the failure of a condition set forth in Section 6.1, and (B) which is not curable or, if curable, is not cured on or prior to the twentieth (20th) day after written notice thereof is given by Lilly to the Company; or

(d) the Company, if (i) any of the representations and warranties of Lilly contained in Section 5 of this Agreement shall fail to be true and correct or (ii) there shall be a breach by Lilly of any covenant of Lilly in this Agreement that, in either case, (A) would result in the failure of a condition set forth in Section 6.2, and (B) which is not curable or, if curable, is not cured on or prior to the twentieth (20th) day after written notice thereof is given by the Company to Lilly.

8.2 Effect of Termination. In the event of the termination of this Agreement pursuant to Section 8.1 hereof, (a) this Agreement (except for this Section 8.2 and Section 9 hereof and any definitions set forth in this Agreement and used in such sections) shall forthwith become void and have no effect, without any liability on the part of any party hereto or its Affiliates, and (b) all filings, applications, and other submissions made pursuant to this Agreement, to the extent practicable, shall be withdrawn from the agency or other Person to which they were made or appropriately amended to reflect the termination of the transactions contemplated hereby; provided, however, that nothing contained in this Section 8.2 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

9. Miscellaneous.

9.1 Survival. The representations and warranties contained in this Agreement shall survive the Closing of the transactions contemplated by this Agreement. The covenants of the parties hereto shall survive until fully performed and discharged, unless otherwise expressly provided herein

9.2 Successors and Assigns. This Agreement may not be assigned by a party hereto without the prior written consent of the other party, provided, however, that Lilly may assign its rights hereunder to a subsidiary that is wholly owned, directly or indirectly, by Lilly (which assignment will not relieve Lilly of any of its obligations hereunder). Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective permitted successors and assigns

any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

9.3 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signatures complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

9.4 Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

9.5 Notices. Unless otherwise provided, any notice required or permitted under this Agreement shall be given in writing and shall be deemed effectively given as hereinafter described (a) if given by personal delivery, then such notice shall be deemed given upon such delivery, (b) if given by mail, then such notice shall be deemed given upon the earlier of (i) receipt of such notice by the recipient or (ii) three days after such notice is deposited in first class mail, postage prepaid, and (c) if given by an internationally recognized overnight air courier, then such notice shall be deemed given one Business Day after delivery to such carrier. All notices shall be addressed to the party to be notified at the address as follows, or at such other address as such party may designate by ten days' advance written notice to the other party:

If to the Company:

Verve Therapeutics, Inc.
201 Brookline Ave, Suite 601
Boston, Massachusetts 02215
Attention: Andrew Ashe, President and Chief Operating Officer

With a copy (which shall not constitute notice) to:

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
Attention: Craig Hilts

If to Lilly:

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
Attention: Senior Vice President, Corporate Business Development

With a copy (which shall not constitute notice) to:

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
Attention: General Counsel

With a copy (which shall not constitute notice) to:

Weil, Gotshal & Manges LLP
767 Fifth Avenue
New York, NY 10153
Attn: Raymond O. Gietz

9.6 Expenses. The parties hereto shall pay their own costs and expenses in connection herewith regardless of whether the transactions contemplated hereby are consummated; it being understood that each of the Company and Lilly has relied on the advice of its own respective counsel.

9.7 Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of the Company and Lilly.

9.8 Severability. Any provision of this Agreement that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof but shall be interpreted as if it were written so as to be enforceable to the maximum extent permitted by applicable law, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. To the extent permitted by applicable law, the parties hereby waive any provision of law which renders any provision hereof prohibited or unenforceable in any respect.

9.9 Entire Agreement. This Agreement, including the signature pages and Exhibits, constitute the entire agreement among the parties hereof with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, both oral and written, between the parties with respect to the subject matter hereof and thereof.

9.10 Further Assurances. The parties shall execute and deliver all such further instruments and documents and take all such other actions as may reasonably be required to carry out the transactions contemplated hereby and to evidence the fulfillment of the agreements herein contained.

9.11 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York. Service of process in connection with any such suit, action or proceeding may be served on each party hereto anywhere in the world by the same methods as are specified for the giving of notices under this Agreement.

[remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties have executed this Agreement or caused their duly authorized officers to execute this Agreement as of the date first above written.

COMPANY: VERVE THERAPEUTICS, INC.

By: /s/ Andrew Ashe

Name: Andrew Ashe

Title: President and Chief Operating Officer

Date: June 14, 2023

LILLY: ELI LILLY AND COMPANY

By: /s/ David A. Ricks

Name: David A. Ricks

Title: Chair and Chief Executive Officer

Lilly Information

Entity Name: Eli Lilly and Company

Address: Lilly Corporate Center

City: Indianapolis

State: Indiana

Zip Code: 46285

Telephone: (317) 276-2000

Tax ID #: 35-0470950

Name in which Shares should be issued: Eli Lilly and Company

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 10, 2023 November 7, 2023

By: /s/ Sekar Kathiresan

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

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Allison Dorval, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Verve Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the period 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 10, 2023 November 7, 2023

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, 2023 September 30, 2023 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 operations of the Company.

Date: August 10, 2023 November 7, 2023

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, 2023** **September 30, 2023** 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 operations of the Company.

Date: **August 10, 2023** **November 7, 2023**

By: /s/ Allison Dorval

Allison Dorval
Chief Financial Officer
(Principal Financial Officer)

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