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 March 31, 2024

OR

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

☐

For the transition period from _____ to _____

Commission File Number: 001-39247

ENLIVEN THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**81-1523849**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
6200 Lookout Road	
Boulder	
,	
CO	**80301**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (720) 647-8519

Not applicable

(Former name, former address, and former fiscal year, if changed since last report)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value per share	**ELVN**	**The Nasdaq Global Select Market**

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

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

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

Large accelerated filer	☐	Accelerated filer	☐

☒ Smaller reporting company

Non-accelerated filer

☒

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 May 1, 2024, the registrant had

47,036,698
shares of common stock, $0.001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this quarterly report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, development plans, planned preclinical studies and clinical trials, future results of clinical trials, expected research and development costs, regulatory strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “would,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements contained in this quarterly report on Form 10-Q include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing, progress and results of clinical trials for ELVN-001 from our BCR-ABL (as defined below) program and ELVN-002 from our HER2 (as defined below) program, and other product candidates we have and may in the future develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the studies or trials will become available, and research and development programs;
- the timing, scope and likelihood of regulatory filings and approvals, including timing of investigational new drug applications ("INDs") and final U.S. Food and Drug Administration (“FDA”) approval of ELVN-001 from our BCR-ABL program and ELVN-002 from our HER2 program and any other future product candidates;
- the timing, scope or likelihood of foreign regulatory filings and approvals;
- our ability to develop and advance current product candidates and programs into, and successfully complete, clinical trials;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the size of the market opportunity for our product candidates, including estimates of the number of patients who suffer from the diseases we are targeting;
- expectations regarding the approval and use of our product candidates in combination with other drugs;
- our ability to secure drug product for combination studies;
- expectations regarding potential for accelerated approval or other expedited regulatory designation;
- our competitive position and the success of competing therapies that are or may become available;
- estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates and our expectations regarding particular lines of therapy;
- plans relating to the further development of our product candidates, including additional indications we may pursue;
- existing regulations and regulatory developments in the United States, Europe and other jurisdictions;
- expectations regarding the impact of health epidemics or other outbreaks, including the COVID-19 pandemic, on our business;
- our expectations regarding the impact of instability in the banking and financial services sector and other macroeconomic trends;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering ELVN-001 from our BCR-ABL program and ELVN-002 from our HER2 program, and other product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual

property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;

• our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for clinical trials;

• our relationships with patient advocacy groups, key opinion leaders, regulators, the research community and payors;

• our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;

• the pricing and reimbursement of ELVN-001 in our BCR-ABL program and ELVN-002 from our HER2 program, and other product candidates we may develop, if approved;

• the rate and degree of market acceptance and clinical utility of ELVN-001 from our BCR-ABL program and ELVN-002 from our HER2 program, and other product candidates we may develop;

• our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;

• our expectations regarding sales of our common stock made pursuant to the Sales Agreement (as defined below);

• our financial performance;

• the period over which we estimate our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operating expenses and capital expenditure requirements;

• our ability to utilize our net operating loss carryforwards ("NOLs") and tax credit carryforwards;

• the impact of laws and regulations; and

• expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 and a smaller reporting company under the Exchange Act (as defined below).

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this quarterly report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this quarterly report on Form 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

In addition, statements such as “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this quarterly report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

Part I – FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

ENLIVEN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(in thousands, except share and per share amounts)

	As of March 31, 2024	As of December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 149,165	$ 100,141
Marketable securities	171,339	153,007
Restricted cash	54	54
Prepaid expenses and other current assets	6,641	2,949
Contingent value right asset	10,000	10,000
Total current assets	337,199	266,151
Property and equipment, net	683	742
Operating lease right-of-use assets	241	320
Deferred offering costs	563	563
Other long-term assets	4,091	4,091
Total assets	$ 342,777	$ 271,867
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,727	$ 532
Accrued expenses and other current liabilities	12,304	15,362
Contingent value right liability	10,000	10,000
Total current liabilities	25,031	25,894
Long-term liabilities	34	67

	25,065	25,961
Total liabilities		
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, par value $ 0.001 ; authorized shares - 10,000,000 ; issued and outstanding shares - none	—	—
Common stock, par value $ 0.001 ; authorized shares - 100,000,000 ; issued and outstanding shares - 46,782,639 and 41,292,027 at March 31, 2024 and December 31, 2023, respectively	47	41
Additional paid-in capital	494,904	400,172
Accumulated other comprehensive (loss) income	(53)	141
Accumulated deficit	(177,186)	(154,448)
Total stockholders' equity	317,712	245,906
Total liabilities and stockholders' equity	$ 342,777	$ 271,867

See accompanying notes to unaudited condensed consolidated financial statements.

ENLIVEN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 19,970	$ 11,880
General and administrative	6,017	4,538
Total operating expenses	25,987	16,418
Loss from operations	(25,987)	(16,418)
Other income (expense), net		
Interest income	3,250	1,694
Other expense	(1)	—
Total other income (expense), net	3,249	1,694
Net loss	(22,738)	(14,724)
Other comprehensive income (loss):		
Net unrealized losses on marketable securities	(194)	—
Comprehensive loss	$ (22,932)	$ (14,724)
Net loss per share, basic and diluted	$ (0.54)	$ (0.80)
Weighted-average shares outstanding, basic and diluted	42,045,608	18,514,644

See accompanying notes to unaudited condensed consolidated financial statements.

ENLIVEN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity (Deficit)
Balance - January 1, 2023	61,730,064	$ 149,749	3,570,019	$ 1	$ 6,038	$ —	$ (82,864)	$ (76,825)
Exercise of common stock options	—	—	55,599	—	140	—	—	140
Vesting of restricted stock awards and stock options	—	—	—	—	73	—	—	73
Conversion of convertible preferred stock to common stock in connection with the Merger	(61,730,064)	(149,749)	18,216,847	18	149,731	—	—	149,749
Issuance of common stock in the Financing Transaction, net of issuance costs of $ 4,955	—	—	12,638,636	13	159,531	—	—	159,544
Issuance of common stock to former stockholders of Imara Inc. in connection with the Merger	—	—	6,625,176	7	80,234	—	—	80,241
Adjustment for change in common stock par value in connection with the Merger	—	—	—	2	(2)	—	—	—
Reverse recapitalization transaction costs	—	—	—	—	(9,044)	—	—	(9,044)
Stock-based compensation	—	—	—	—	2,262	—	—	2,262
Net loss	—	—	—	—	—	—	(14,724)	(14,724)
Balance - March 31, 2023	—	$ —	41,106,277	$ 41	$ 388,963	$ —	$ (97,588)	$ 291,416

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance - January 1, 2024	—	$ —	41,292,027	$ 41	$ 400,172	$ 141	$ (154,448)	$ 245,906
Exercise of common stock options	—	—	130,780	—	320	—	—	320
Vesting of restricted stock units	—	—	2,688	—	—	—	—	—

Vesting of restricted stock awards and stock options	—	—	—	—	73	—	—	73
Issuance of common stock and Pre-Funded Warrants in the Private Placement, net of issuance costs of $170	—	—	5,357,144	6	89,824	—	—	89,830
Stock-based compensation	—	—	—	—	4,515	—	—	4,515
Net loss	—	—	—	—	—	—	(22,738)	(22,738)
Other comprehensive loss	—	—	—	—	—	(194)	—	(194)
Balance - March 31, 2024	—	$ —	46,782,639	$ 47	$ 494,904	$ (53)	$ (177,186)	$ 317,712

See accompanying notes to unaudited condensed consolidated financial statements.

ENLIVEN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (22,738)	$ (14,724)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	79	67
Stock-based compensation	4,515	2,262
Non-cash lease expense	79	—
Amortization of premiums and discounts on marketable securities, net	(661)	—
Changes in operating assets and liabilities:		
Prepaid expenses, other current and long-term assets	(3,642)	(6,088)
Operating lease liabilities	(83)	(1)
Accounts payable	2,155	492
Accrued expenses and other liabilities	(3,065)	(2,852)
Net cash used in operating activities	(23,361)	(20,844)
Cash flows from investing activities:		
Maturities of marketable securities	38,913	—
Purchases of marketable securities	(56,778)	—
Purchases of property and equipment	(20)	(31)
Net cash used in investing activities	(17,885)	(31)
Cash flows from financing activities:		
Proceeds from exercise of stock options	270	140
Proceeds from issuance of common stock and Pre-Funded Warrants in the Private Placement, net of issuance costs	90,000	—
Proceeds from the Financing Transaction, net of issuance costs	—	162,900

Cash acquired in connection with the reverse recapitalization	—	81,821
Payment of reverse recapitalization transaction costs	—	(7,420)
Net cash provided by financing activities	90,270	237,441
Net increase in cash, cash equivalents and restricted cash	49,024	216,566
Cash, cash equivalents and restricted cash at the beginning of the period	100,195	75,590
Cash, cash equivalents and restricted cash at the end of the period	$ 149,219	$ 292,156
Components of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 149,165	$ 292,102
Restricted cash	54	54
Total cash, cash equivalents and restricted cash	$ 149,219	$ 292,156
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of convertible preferred stock to common stock	$ —	$ 149,749
Issuance costs related to the Private Placement included in accounts payable and accrued expenses and other current liabilities	$ 170	$ —
Issuance costs related to the Financing Transaction included in accounts payable	$ —	$ 1,534
Transaction costs related to the reverse recapitalization included in accounts payable and accrued expenses and other current liabilities	$ —	$ 1,316
Receivables from stock option exercises included in prepaid expenses and other current assets	$ 50	$ —

See accompanying notes to unaudited condensed consolidated financial statements.

ENLIVEN THERAPEUTICS, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization, Description of Business and Liquidity

Business

Enliven Inc. (formerly, Enliven Therapeutics, Inc.) ("Former Enliven") was incorporated in the State of Delaware on June 12, 2019 . Enliven Therapeutics, Inc. (formerly, Imara Inc.) (the "Company") is headquartered in Boulder, Colorado. The Company is a clinical-stage biopharmaceutical company focused on the discovery and development of small molecule inhibitors to help people with cancer not only live longer, but live better. The Company aims to address existing and emerging unmet needs with a precision oncology approach that improves survival and enhances overall well-being. Its discovery process combines deep insights in clinically validated biological targets and differentiated chemistry with the goal of designing therapies for unmet needs.

Since its inception, the Company has devoted substantially all of its efforts to research and development activities, business planning, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these activities. To date, the Company has funded its operations primarily through private placements of its common and convertible preferred stock.

The Merger, Exchange Ratio and Financing Transaction

On October 13, 2022, the Company entered into an agreement and plan of merger ("Merger Agreement" and such transactions considered by the Merger Agreement, the "Merger") with Former Enliven.

On February 23, 2023, the Company completed the Merger with Former Enliven in accordance with the Merger Agreement. Prior to the effective time of the Merger, the Company effected a 1-for-4 reverse stock split (the "Reverse Stock Split"), and right after the Merger, the Company changed its name to Enliven Therapeutics, Inc. Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, (a) each outstanding share of Former Enliven common stock (including common stock issued upon the conversion of its preferred stock) was converted into the right to receive a number of shares of the Company's common stock ("Company Common Stock") (after giving effect to the Reverse Stock Split) equal to the exchange ratio per the Merger Agreement; and (b) each then outstanding Former Enliven stock option that had not previously been exercised prior to the closing of the Merger was assumed by the Company. At closing of the Merger, the Company issued an aggregate of

34,426,351
shares of Company Common Stock to Former Enliven's stockholders, based on an exchange ratio of approximately

0.2951
shares of Company Common Stock for each share of Former Enliven common stock outstanding immediately prior to the Merger, including those shares of common stock issued upon conversion of the Former Enliven preferred stock, resulting in

41,011,501

shares of Company Common Stock being issued and outstanding immediately following the effective time of the Merger. The Company also assumed all of the outstanding and unexercised stock options to purchase shares of Former Enliven common stock. The assumed options continue to be governed by the terms of the 2019 Equity Incentive Plan (as further discussed in Note 12) under which the options were originally granted, with such options hence forth representing the right to purchase a number of shares of Company Common Stock equal to approximately

0.2951
multiplied by the number of shares of Former Enliven common stock previously represented by such options.

The Merger was accounted for as a reverse recapitalization in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). Under this method of accounting, Former Enliven was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the expectation that, immediately following the Merger: (i) Former Enliven stockholders will own a substantial majority of the voting rights; (ii) Former Enliven will designate a majority (

eight
of nine) of the initial members of the board of directors of the combined company; (iii) Former Enliven's executive management team will become the management team of the combined company; and (iv) the combined company will be named Enliven Therapeutics, Inc. and be headquartered in Boulder, Colorado. Accordingly, for accounting purposes, the Merger was treated as the equivalent of Former Enliven issuing stock to acquire the net assets of the Company. As a result of the Merger, the net assets of the Company were recorded at their acquisition-date fair value in the financial statements of Former Enliven and the reported operating results prior to the Merger will be those of Former Enliven. Historical common share figures of Former Enliven have been retroactively restated based on the exchange ratio of approximately

0.2951
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On February 23, 2023, prior to the effective time of the Merger, the Company entered into a Contingent Value Rights Agreement (the "CVR Agreement") with a rights agent, pursuant to which the Company's pre-Merger common stockholders received one contingent value right (each, a "CVR") for each outstanding share of the Company's common stock held by such stockholder as of February 22, 2023. Each CVR represents the contractual right to receive payments upon the occurrence of certain events related to

the Company's sale of certain assets prior to the completion of the Merger, in each case subject to, and in accordance with, the terms and conditions of the CVR Agreement. Under the CVR Agreement, the Company is only liable to the CVR holders once it has received payments from the third-party that purchased the assets, which will only occur upon the third-party achieving certain development milestones related to the assets purchased. In accordance with the CVR Agreement, any distributions to the Company for these milestone payments are then subsequently remitted to the CVR holders, net of permitted deductions, if any. Pursuant to the terms of an asset purchase agreement with a third-party, the Company is eligible to receive two potential milestones, one for $

10.0
million and a second for $

50.0
million. The Company has no involvement, control or influence over the development of such assets.

Concurrently with the execution of the Merger Agreement, and in order to provide Former Enliven with additional capital for its development programs prior to the closing of the Merger, certain new and current investors purchased an aggregate of $

164.5
million of common stock of Former Enliven (the "Financing Transaction").

Risks and uncertainties

The Company is subject to risks common to development-stage companies in the biotechnology industry including, but not limited to, risks of failure of preclinical studies and clinical trials, new technological innovations, protection of proprietary technology, dependence on key personnel, reliance on third-party organizations, risks of obtaining regulatory approval for any product candidate that it may develop, compliance with government regulations and the need to obtain additional financing.

The Company continues to closely monitor macroeconomic and geopolitical developments, including inflation, instability in the banking and financial services sector, tightening of the credit markets, the Russia-Ukraine conflict and widening conflict in the Middle East, and COVID-19. The Company intends to establish clinical trial sites in Israel, which may face enrollment, retention, operational or other difficulties due to conflicts within the region, including, for example, difficulties importing clinical trial drug through Israeli customs, difficulties with patient enrollment, or difficulties with patients or medical personnel accessing appropriate medical facilities. The extent of the impact of these developments on the Company's business, operations and research and development timelines and plans remains uncertain and will depend on numerous factors, including the impact, if any, on the Company's personnel, responses of governmental entities, and the responses of third parties, such as contract research organizations, contract manufacturing organizations and other third parties with whom the Company does business. Any prolonged material disruption to the Company's employees or suppliers could adversely impact the Company's development activities, financial condition and results of operations, including its ability to obtain financing. The Company is monitoring the potential impact of these developments on its business and consolidated financial statements. To date, the Company has not experienced material business disruptions or incurred impairment losses in the carrying values of its assets as a result of these developments, and it is not aware of any specific related event or circumstance that would require it to revise its estimates reflected in these condensed consolidated financial statements.

Liquidity considerations

In order to complete the development of the Company's product candidates and to build the sales, marketing and distribution infrastructure that the Company believes will be necessary to commercialize its product candidates, if approved, the Company will require substantial additional capital. Until the Company can generate a sufficient amount of revenue from the commercialization of its product candidates, the Company may seek to raise any necessary additional capital through equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, the Company is unable to estimate the exact amount and timing of its capital requirements. The Company does not expect to generate any meaningful revenue unless and until the Company obtains regulatory approval of and commercializes any of its product candidates, and the Company does not know when, or if, that will occur.

The Company has incurred significant losses and negative cash flows from operations since inception. As of March 31, 2024, the Company had an accumulated deficit of $

177.2
million. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future as the Company continues to develop its product candidates. The Company currently expects that its cash, cash equivalents and marketable securities of $

320.5
million as of March 31, 2024 will be sufficient to fund operating expenses and capital requirements for at least 12 months from the date the unaudited condensed consolidated financial statements are issued.

On June 23, 2023, the Company filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission (the "SEC"), which was declared effective by the SEC on July 3, 2023, which allows the Company to undertake various equity and debt offerings up to $

400.0

million. On June 23, 2023, the Company also entered into an Open Market Sale Agreement℠ (the “Sales Agreement”) with Jefferies LLC (the "Sales Agent”), pursuant to which the Company may offer and sell shares of Company Common Stock, from time to time through an “at-the-market” program under the Securities Act of 1933 (the “Securities Act”), having an aggregate offering price of up to $

200.0

million through the Sales Agent. Sales of Company Common Stock made pursuant to the Sales Agreement, if any, will be made under the Company’s shelf registration statement on Form S-3. On July 6, 2023, the Company filed a prospectus supplement to the shelf registration statement that covers the offering, issuance and sale of Company Common Stock under the Sales Agreement.

Refer to Note 10 for further discussion.

2. Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited condensed consolidated financial statements as of March 31, 2024 and for the three months ended March 31, 2024 and 2023 have been prepared in conformity with U.S. GAAP, for interim financial information and pursuant to Article 10 of Regulation S-X of the Securities Act. Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed consolidated financial statements have been prepared on the same basis as the Company’s audited financial statements and include only normal and recurring adjustments that the Company believes are necessary to fairly state the Company’s financial position and the results of its operations and cash flows. The results for the three months ended March 31, 2024 are not necessarily indicative of the results expected for the full fiscal year or any subsequent interim period. The condensed consolidated balance sheet as of December 31, 2023 has been derived from the audited financial statements at that date but does not include all disclosures required by U.S. GAAP for complete financial statements. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with the Company’s audited financial statements as of and for the year ended December 31, 2023 included in the Company’s Annual Report on Form 10-K filed with the SEC on March 14, 2024. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP, as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of income and expense during the reporting period. The most significant estimates relate to stock-based compensation and accrued research and development expenses. Management evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors, including the current economic environment, and makes adjustments when facts and circumstances dictate. Actual results may differ from those estimates or assumptions.

Cash and cash equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents are recorded at cost, which approximates fair value. As of March 31, 2024 and December 31, 2023, cash and cash equivalents consisted primarily of checking and money market funds composed of U.S. government obligations.

Restricted cash

The Company classifies all cash whose use is limited by contractual provisions as restricted cash. Restricted cash arises from the requirement for the Company to maintain cash of $

54,000

as collateral for a sublease with the facility’s landlord. As of March 31, 2024 and December 31, 2023, $

54,000

of restricted cash was reflected as current assets in the condensed consolidated balance sheets.

Marketable securities

The Company’s marketable securities primarily consist of U.S. Treasury securities. The Company classifies its marketable securities as available-for-sale and records such assets at estimated fair value in the condensed consolidated balance sheets, with unrealized

gains and losses, if any, reported as a component of other comprehensive income (loss) within the condensed consolidated statements of operations and comprehensive loss and as a separate component of stockholders' equity. The Company classifies marketable securities with remaining maturities greater than one year as current assets due to their highly liquid nature and because such marketable securities represent the investment of cash that is available to fund the Company's current operations. Interest and dividends on marketable securities are included in interest income. The cost of marketable securities sold is based on the specific identification method, with any realized gains and losses recorded as interest income. There were no realized gains and losses during the periods presented.

At each balance sheet date, the Company assesses available-for-sale debt securities in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in net income (loss). For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through net income (loss). For available-for-sale securities that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded as an allowance in interest income. There have been no impairment or credit losses recognized during the periods presented.

Concentrations of credit risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities, as well as restricted cash. The Company maintains deposits in U.S. federally insured financial institutions in excess of federally insured limits. The Company has established guidelines regarding approved investments, credit quality, diversification, liquidity and maturities of investments, which are designed to maintain safety and liquidity. Although management currently believes that the financial institutions with whom it does business will be able to fulfill their commitments to the Company, there is no assurance that those institutions will be able to continue to do so. As of March 31, 2024, the Company has not experienced any losses in its accounts and believes it is not exposed to significant credit risk on its cash balances.

Fair value measurements

Financial assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the price the Company would receive to sell an investment in a timely transaction or pay to transfer a liability in a timely transaction with an independent buyer in the principal market, or in the absence of a principal market, the most advantageous market for the investment or liability. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels of the fair value hierarchy are as follows:

- Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2—Quoted prices (other than quoted prices in Level 1) in markets that are not considered to be active or financial instrument valuations for which all significant inputs are observable, either directly or indirectly; and
- Level 3—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

Financial instruments are categorized in their entirety based on the lowest level of input that is significant to the fair value measurement. The assessment of the significance of a particular input to the fair value measurement requires judgment and considers factors specific to the investment. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3.

The Company monitors the availability of inputs that are significant to the measurement of fair value to assess the appropriate categorization of financial instruments within the fair value hierarchy. Changes in economic conditions or model-based valuation

techniques may require the transfer of financial instruments from one fair value level to another. In such instances, the Company's policy is to recognize significant transfers between levels at the end of the reporting period. The significance of transfers between levels is evaluated based upon the nature of the financial instrument and size of the transfer relative to total net assets available for benefits.

The Company's cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate their fair value due to their short maturities.

Deferred offering costs

Deferred offering costs represent legal, accounting and other direct costs related to the Company's efforts to raise capital through a public or private sale of the Company's common stock. These costs are generally deferred until the completion of the applicable offering, at which time such costs are reclassified to additional paid-in-capital as a reduction of the proceeds. In the instance where a planned equity financing is abandoned, terminated or significantly delayed, the deferred offering costs are recorded as expense in the period of such determination .

Property and equipment, net

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Expenditures for repairs and maintenance are expensed as incurred. When assets are retired or disposed of, the assets and related accumulated depreciation are eliminated from the accounts, and any resulting gain or loss is included in the determination of net income or loss. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset.

The Company's property and equipment consist of laboratory equipment and employee-related computers with estimated useful lives of three to five years .

Impairment of long-lived assets

The Company evaluates long-lived assets, which consist of laboratory equipment and computers, for impairment at least annually, or whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. As of March 31, 2024,

no
impairments have been recognized in the Company's financial statements.

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company records the associated lease liability and corresponding right-of-use ("ROU") asset upon commencement of the lease using the implicit rate or a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. Certain leases include renewal options at the lessee's election, which are included when recording the lease if it is reasonably certain that the renewal option will be exercised. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding ROU assets are recognized on the balance sheet at the commencement date of the lease based on the present value of lease payments over the expected lease term. Lease cost is recognized on a straight-line basis over the lease term and variable lease payments are recognized as operating expenses in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in proportion to the space leased by the Company. The Company has elected the practical expedient not to separate between lease and non-lease components.

Operating ROU assets are reflected in operating lease right-of-use assets on the balance sheets. Operating lease liabilities are reflected in accrued expenses and other current liabilities and long-term liabilities on the balance sheets.

CVR asset and liability

The Company evaluates its contracts to determine if those contracts qualify as derivatives under ASC 815, *Derivatives and Hedging*. For derivative financial instruments that are accounted for as assets or liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date. Any changes in fair value are recorded as other income or expense for each reporting period. Derivative instrument assets or liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is probable within the next 12 months from the balance sheet date. The Company determined that certain contingent payments under the CVR Agreement and milestone payments related to the asset sales prior to the merger qualified as derivatives under ASC 815. Upon such time that these payments are assessed a fair value, they would be recorded as a liability and asset, respectively, on the balance sheet. These values are then remeasured for future expected payout or receipt, as well as the increase in fair value due to the time value of money. These gains or losses, if any, are recognized in the consolidated statements of operations and comprehensive loss within Other income (expense), net.

The Company applies a scenario-based method and weighs them based on the possible achievement of certain milestones for both the asset and liability recognized. The fair value measurements are based on significant inputs not observable in the market and thus represent a Level 3 measurement as defined in ASC 820, *Fair Value Measurement*. The estimated value of the CVR and milestone consideration are based upon available information and certain assumptions, which the Company's management believes are reasonable under the circumstances.

Convertible preferred stock

The Company classifies convertible preferred stock outside of stockholders' equity on its balance sheet as the requirements of triggering a deemed liquidation event are not within the Company's control. In the event of a deemed liquidation event, the proceeds from the event are distributed in accordance with liquidation preferences. The Company records the issuance of convertible preferred stock at the issuance price less related issuance costs and less any discount arising on allocation of proceeds to one or more derivative features. Immediately prior to the effective time of the Merger, all outstanding shares of Former Enliven's convertible preferred stock were converted into shares of Former Enliven's common stock, which were subsequently converted into Company Common Stock upon the closing of the Merger (see Note 11).

Research and development expenses

The Company expenses research and development costs as incurred. Research and development expenses consist primarily of costs incurred for the discovery and development of its product candidates and include consultants and supplies to conduct clinical, preclinical, and non-clinical studies, costs to acquire, develop and manufacture supplies for preclinical and clinical testing and other studies, expenses incurred under agreements with contract research organizations, and salaries and related costs, including stock-based compensation, as well as depreciation and other allocated facility-related and overhead expenses. Advance payments for goods or services for future research and development activities are deferred and expensed as the goods are delivered or the related services are performed.

The Company estimates clinical and preclinical study expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on the Company's behalf. In addition, clinical, preclinical, and non-clinical study materials are manufactured by contract manufacturing organizations. In accruing for these services, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. These estimates are based on communications with the third-party service providers and the Company's estimates of accrued expenses and on information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly.

Stock-based compensation

The Company measures and records the expense related to stock-based payment awards based on the estimated grant date fair value of those awards. The Company recognizes stock-based compensation expense over the requisite service period on a straight-line basis for all stock-based awards to employees, non-employees and directors, including grants of stock options and other stock-based awards. The Company uses the Black-Scholes option pricing model to determine the fair value of the stock awards. The Black-Scholes option pricing model requires the Company to make assumptions and judgments about the variables used in the calculations, including the expected term, expected volatility of its common stock, risk-free interest rate and expected dividend yield. As the stock-based compensation is based on awards ultimately expected to vest, it is reduced by forfeitures, which the Company accounts for as they occur.

The Company classifies equity-based compensation expense in the statement of operations and comprehensive loss in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified.

Black-Scholes requires the use of subjective assumptions, which determine the fair value of stock-based awards. These assumptions include:

- Expected Term—The expected term represents the period that the Company's options are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term). The Company has very limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants.
- Expected Volatility—The expected stock price volatilities are estimated based on the historical and implied volatilities of comparable publicly traded companies as the Company does not have sufficient history of trading its common stock.
- Risk-Free Interest Rate—The risk-free interest rates are based on U.S. Treasury yields in effect at the grant date for notes with comparable terms as the awards.
- Expected Dividend Yield—The Company has never paid dividends on its common stock and has no plans to do so in the future. Therefore, the Company used an expected dividend of

zero
.

The assumptions underlying these valuations represented the Company's board of directors' and management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if the Company had used significantly different assumptions or estimates, the fair value of its stock-based compensation expense could be materially different.

Income taxes

Income taxes are accounted for using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or the Company's tax return. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period of enactment. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The Company has generated significant net losses since its inception and accordingly has not recorded a provision for income taxes.

The Company evaluates its uncertain tax positions using the provisions of ASC Topic 740*, Income taxes,* which prescribes a recognition threshold that a tax position is required to meet before being recognized in the consolidated financial statements by using a "more-likely-than-not" criteria for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company recognizes a tax benefit from an uncertain tax position if it is more likely than not that the tax position will be sustained upon examination by the tax authorities, based on the merits of the position. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, which are considered appropriate as well as the related net interest and penalties. As of March 31, 2024, there have been

no
interest or penalties charged in relation to the unrecognized tax benefits.

Net loss per share

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period, including pre-funded warrants to purchase shares of common stock. The weighted-average number of shares of common stock outstanding used in the basic net loss per share calculation does not include unvested restricted common stock as these shares are considered contingently issuable shares until they vest.

Diluted net loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock, stock options, unvested early exercised common stock and unvested restricted common stock, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive

securities are not included in the calculation as the impact is anti-dilutive. For all periods presented, basic and diluted net loss per share were the same, as any additional share equivalents would be anti-dilutive.

Segments

The Company operates in

one

segment and, accordingly, no segment disclosures have been presented herein. The Company's long-lived assets are primarily located in the United States. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating and evaluating financial performance.

Comprehensive income (loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, which includes net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes unrealized gains and losses on marketable securities, other than losses attributable to a credit loss, which are included in other income and expense. The Company's only component of other comprehensive income (loss) is related to unrealized gains and losses on marketable securities.

Emerging growth company status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private companies. The Company has 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 that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Accounting pronouncements not yet adopted

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Updated and Simplification Initiative*, which amends the disclosure or presentation requirements related to various subtopics in the FASB ASC. ASU 2023-06 was issued in response to the SEC's August 2018 final rule that updated and simplified disclosure requirements and is intended to align U.S. GAAP requirements with those of the SEC and to facilitate the application of U.S. GAAP for all entities. For entities subject to the SEC's existing disclosure requirements and for entities required to file or furnish financial statements with or to the SEC in preparation for the sale of or for purposes of issuing securities that are not subject to contractual restrictions on transfer, the effective date for each amendment will be the date on which the SEC removes that related disclosure from its rules. However, if by June 30, 2027, the SEC has not removed the related disclosure from its regulations, the amendments will be removed from the Codification and not become effective for any entity. The Company is currently evaluating the impact of this guidance, but does not expect the adoption of this guidance to have a material impact on its consolidated financial statements and disclosures.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which are intended to improve reportable segment disclosure requirements. ASU 2023-07 expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. The amendments are effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The amendments should be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact that this guidance will have on its consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* ASU 2023-09 improves the transparency and decision usefulness of income tax disclosures by requiring consistent categorization and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid, disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. This guidance will be effective for the annual periods beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact that this guidance will have on its consolidated financial statements and disclosures.

3. The Merger

As described in Note 1, Former Enliven merged with the Company on February 23, 2023. The Merger was accounted for as a reverse recapitalization with Former Enliven as the accounting acquirer. The primary pre-combination assets of the Company were cash and cash equivalents. Under reverse recapitalization accounting, the assets and liabilities of the Company were recorded at their fair value, which approximated book value due to the short-term nature of the instruments. No goodwill or intangible assets were recognized. Consequently, the unaudited condensed consolidated financial statements of the Company reflect the operations of Former Enliven for accounting purposes together with a deemed issuance of shares, equivalent to the shares held by the former stockholders of the legal acquirer and a recapitalization of the equity of the accounting acquirer.

The following table summarizes the fair value of identifiable assets acquired and liabilities assumed as part of the recapitalization (in thousands):

Cash and cash equivalents	$ 81,821
Other current assets	1,044
Accrued liabilities	(2,624)
Net assets acquired	$ 80,241

In connection with the Merger and concurrent Financing Transaction, the Company incurred reverse recapitalization transaction costs of $ 9.0 million and issuance costs of $ 5.0 million, which were capitalized and recorded on the condensed consolidated balance sheets as deferred offering costs. On February 23, 2023, at the close of the Merger, the deferred offering costs were recorded as contra equity.

In addition, the Company incurred $ 1.3 million in stock-based compensation expense as a result of the acceleration of vesting of stock options at the time of the Merger. This amount was recorded in general and administrative expense on the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2023 and year ended December 31, 2023.

4. Fair Value Measurements

The following tables set forth the fair value of the Company's financial assets measured at fair value on a recurring basis and indicates the level within the fair value hierarchy utilized to determine such values (in thousands):

As of March 31, 2024	Total	Level 1	Level 2	Level 3
Cash equivalents:				
U.S. Treasury backed money market funds	$ 143,427	$ 143,427	$ —	$ —
U.S. Treasury securities	4,977	4,977	—	—
Marketable securities:				
U.S. Treasury securities	171,339	171,339	—	—
Total	$ 319,743	$ 319,743	$ —	$ —

As of December 31, 2023	Total	Level 1	Level 2	Level 3
Cash equivalents:				

U.S. Treasury backed money market funds	99,388	99,388	—	—
	$	$	$	$
Marketable securities:				
U.S. Treasury securities	153,007	153,007	—	—
Total	252,395	252,395	—	—
	$	$	$	$

CVR asset and liability

Upon the completion of the Merger in February 2023, the Company assessed the fair value of the payments to be made under the CVR Agreement to be

zero

as the Company had determined the payments were not probable. During the fourth quarter of 2023, the Company assessed the fair value of the first milestone under the asset purchase agreement at

100

% based upon certain information received from the third-party indicating that the milestone was likely to be achieved in early 2024. As such, the Company estimated the fair value of the CVR asset and liability for this first milestone and recorded a $

10.0

million CVR asset and $

10.0

million CVR liability on its consolidated balance sheet as of December 31, 2023. In March 2024, the Company received formal notification from the third-party that the first milestone event as set forth in the asset purchase agreement had been achieved, and the Company

received the $

10.0

million milestone payment in April 2024. As the second milestone event under this asset purchase agreement relates to the future potential commercialization of the assets,

no

value was attributed to this milestone as of March 31, 2024 and December 31, 2023. As of March 31, 2024 and December 31, 2023, the Company's condensed consolidated balance sheets reflected a $

10.0

million CVR asset and $

10.0

million CVR liability, and

no

CVR payments have been made under the CVR Agreement. Pursuant to the terms of the CVR Agreement, the Company has 45 days from the end of the calendar quarter in which funds are received to deliver the milestone proceeds, net of permitted deductions, if any, to the rights agent for distribution to the CVR holders.

5. Marketable Securities

The Company’s marketable securities are classified as available-for-sale and are stated at fair value. Marketable securities consisted of the following (in thousands):

As of March 31, 2024	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	1 or less	$ 171,392	$ 7	$ (60)	$ 171,339
Total		$ 171,392	$ 7	$ (60)	$ 171,339

As of December 31, 2023	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	1 or less	$ 152,866	$ 147	$ (6)	$ 153,007
Total		$ 152,866	$ 147	$ (6)	$ 153,007

6. Leases

Facility lease

In June 2020, the Company executed a sublease agreement for

6,782

square feet of office and laboratory space, which was set to expire on December 30, 2021 . In March 2021, the Company amended its sublease agreement, increasing the leased space by

2,495

square feet to

9,277

square feet and monthly rent to $

12,000

. In April 2022, the lease term was extended to December 30, 2024 . In addition, the Company’s leased space was increased to

18,170

square feet commencing in July 2022, and the rental payments were increased by an equally proportionate amount to reflect the increase in floor space. The monthly rent is subject to annual increases through the lease term. The Company is required to pay base rent expense as well as its

proportionate share of the facilities operating expenses. The non-lease components, consisting primarily of common area maintenance, are paid separately based on actual costs incurred. Therefore, the variable non-lease components were not included in the ROU assets and lease liabilities and are reflected as expense in the period incurred. The incremental borrowing rate used to calculate the Company's ROU assets and lease liabilities is

4

%. The incremental borrowing rate was estimated based on the Company's estimated borrowing rate on a collateralized loan. As of March 31, 2024, the remaining ROU assets and lease liabilities were $

0.2

million and $

0.3

million, respectively. As of December 31, 2023, the remaining ROU assets and lease liabilities were $

0.3

million and $

0.3

million, respectively.

Under the facility sublease, the Company recognized rent expense of $

81,000

and $

81,000

for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, the future minimum lease payments under the facilities operating sublease were as follows (in thousands):

	As of March 31, 2024
Year ending December 31,	
2024 (remaining nine months)	$ 256
Thereafter	—
Total future minimum lease payments	256
Less: amount representing interest	(4)
Present value of lease liabilities	252
Less: current portion of lease liabilities	(252)
Lease liabilities, non-current	$ —

No

impairment losses were recognized during the three months ended March 31, 2024 and 2023.

7. Property and Equipment, Net

Property and equipment, net consisted of the following (dollar amounts in thousands):

	Estimated Useful Life in Years	As of March 31, 2024	As of December 31, 2023
Laboratory equipment	5	$ 1,191	$ 1,191
Computer equipment	3	242	222
Property and equipment, gross		1,433	1,413
Less: accumulated depreciation		(750)	(671)
Property and equipment, net		$ 683	$ 742

Depreciation expense was $

79,000

and $

67,000

for the three months ended March 31, 2024 and 2023, respectively.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	As of March 31, 2024	As of December 31, 2023
Accrued employee compensation costs	$ 1,808	$ 3,328
Accrued research and development costs	8,835	10,433
Lease liability	252	335
Accrued legal and professional fees	963	902
Other	446	364
Accrued expenses and other current liabilities	$ 12,304	$ 15,362

9. Commitments and Contingencies

Litigation

From time to time, the Company may be involved in legal proceedings or be subject to claims arising in the ordinary course of its business. The Company is not currently a party to any legal proceedings. Regardless of outcome, any proceedings or claims can have an adverse impact on the Company because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Indemnification agreements

In the ordinary course of business, the Company has provided and may provide indemnification of varying scope and terms to vendors, consultants, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is

not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of March 31, 2024 and December 31, 2023.

10. Common Stock

As of March 31, 2024, the Company's Amended and Restated Certificate of Incorporation authorized the Company to issue

100,000,000
shares of $

0.001
par value common stock, of which

46,782,639

shares were issued and outstanding. As of March 31, 2024 and December 31, 2023, there were

60,830
and

86,153
shares subject to repurchase, respectively. The liability related to shares subject to repurchase totaled $

0.3
million and $

0.4
million as of March 31, 2024 and December 31, 2023, respectively, of which $

0.1
million and $

0.1
million were recorded as long-term liabilities as of March 31, 2024 and December 31, 2023, respectively.

Each share of common stock entitles the holder to

one
vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company's board of directors, if any.

No

dividends have been declared or paid by the Company through March 31, 2024.

Upon completion of the Merger on February 23, 2023, the Company issued an aggregate of

34,426,351
shares of its common stock to Former Enliven stockholders, based on an exchange ratio of approximately

0.2951
share of the Company's common stock for each share of Former Enliven common stock outstanding immediately prior to the Merger, including those shares of common stock issued upon conversion of the Former Enliven preferred stock (

18,216,847
common shares) and those shares issued with its pre-merger financing of $

164.5
million (

12,638,636
common shares).

On June 23, 2023, the Company entered into the Sales Agreement with the Sales Agent, pursuant to which the Company may offer and sell shares of its common stock, from time to time, having an aggregate offering price of up to $

200.0
million through the Sales Agent. Sales of the Company's common stock made pursuant to the Sales Agreement, if any, will be made under the Company's shelf registration statement on Form S-3, which was declared effective by the SEC on July 3, 2023. As of March 31, 2024, there have been

no
sales of common stock pursuant to the Sales Agreement.

On March 21, 2024, the Company sold in a private placement (the "Private Placement")

5,357,144
shares of its common stock at $

14.00
per share and pre-funded warrants (the "Pre-Funded Warrants") to purchase

1,071,505
shares of its common stock at a price of $

13.999
per Pre-Funded Warrant, resulting in aggregate gross proceeds of $

90.0
million, before estimated issuance costs of $

0.2
million. The Pre-Funded Warrants have an exercise price of $

0.001
per share, subject to proportional adjustments in the event of stock splits or combinations or similar events, are immediately exercisable on the date of issuance and remain exercisable until exercised in full. As of March 31, 2024, all of the Pre-Funded Warrants related to the Private Placement remain unexercised and outstanding.

The Pre-Funded Warrants met the permanent equity criteria classification and, therefore, were classified as a component of permanent stockholders' equity within additional paid-in capital. The Pre-Funded Warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, the Pre-Funded Warrants do not provide any guarantee of value or return.

The Company had the following shares of common stock reserved for future issuance:

	As of March 31, 2024	As of December 31, 2023
Issuance of common stock upon exercise of stock options	7,755,740	5,817,339
Issuance of common stock upon vesting of restricted stock units	95,817	78,505
Equity awards available for grant under equity plans	1,322,398	1,574,426
Shares available for issuance under the Employee Stock Purchase Plan	809,890	402,757

Total common stock reserved for future issuance	9,983,845	7,873,027

11. Preferred Stock and Convertible Preferred Stock

Preferred stock

As of March 31, 2024 and December 31, 2023, the Company was authorized to issue up to

10,000,000

shares of preferred stock at a par value of $

0.001

. As of March 31, 2024 and December 31, 2023,

no

shares of preferred stock were issued and outstanding.

Convertible preferred stock

On February 23, 2023, Former Enliven completed the Merger with the Company in accordance with the Merger Agreement. Under the terms of the Merger Agreement, immediately prior to the effective time of the Merger, each share of Former Enliven's convertible preferred stock was converted into a share of Former Enliven's common stock. At closing of the merger, the Company issued an aggregate of

34,426,351

shares of its common stock to Former Enliven stockholders, based on an exchange ratio of approximately

0.2951

shares of the Company's common stock for each share of Former Enliven's common stock outstanding immediately prior to the Merger, including those shares of common stock issued upon conversion of Former Enliven's convertible preferred stock.

12. Stock-Based Compensation

Equity Incentive Plans

2019 Equity Incentive Plan

In July 2019, Former Enliven adopted the 2019 Equity Incentive Plan (the "2019 Plan") pursuant to which its board of directors may grant non-statutory stock options, stock appreciation rights, restricted stock, and restricted stock units to employees and non-employees and incentive stock options only to employees. The 2019 Plan was terminated as of the close of the Merger, and

no

shares remain available for future issuance under the 2019 Plan. Any options outstanding under the 2019 Plan remained outstanding and effective.

2016 Stock Incentive Plan

The Company's 2016 Stock Incentive Plan (the "2016 Plan") provided for the grant of restricted stock, restricted stock units, stock appreciation rights, incentive stock options, non-statutory stock options and other stock-based awards to employees, officers, members of the board of directors, consultants and advisors of the Company. As of the effective date of the 2020 Equity Incentive Plan,

no

shares remained available for future issuance under the 2016 Plan. Any options or awards outstanding under the 2016 Plan remained outstanding and effective.

2020 Equity Incentive Plan

On October 1, 2019, the Company's board of directors adopted, and on February 26, 2020 the Company's stockholders approved, the 2020 Equity Incentive Plan, which became effective on March 11, 2020 (the "2020 Plan"). The 2020 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards.

On November 8, 2022, the Company's board of directors adopted, and on February 22, 2023, the Company's stockholders approved, the amendment and restatement of the 2020 Plan. Following the Reverse Stock Split effected on February 23, 2023, the number of shares reserved for issuance under the 2020 Plan is equal to

4,275,000

shares of the Company's common stock. The number of shares reserved shall be annually increased on the first day of each fiscal year, beginning with the fiscal year commencing on January 1, 2024 and continuing until, and including, the fiscal year commencing January 1, 2032, equal to the least of (i)

4.5

% of the number of shares of the Company's common stock outstanding on the first day of such fiscal year and (ii) an amount determined by the Company's board of directors. The shares of common stock underlying any awards that expire, terminate, or are otherwise surrendered, cancelled, forfeited or repurchased by the Company under the 2020 Plan will be added back to the shares of common stock available for issuance under the 2020 Plan. As of March 31, 2024,

1,322,398

shares of the Company's common stock remained available for issuance under the 2020 Plan.

Awards granted under the Company's equity plans expire no later than 10 years from the date of grant. Options and restricted stock granted to employees typically vest over a four-year period but may have been granted with different vesting terms.

2020 Employee Stock Purchase Plan

On October 1, 2019, the Company's board of directors adopted, and on February 26, 2020, the Company's stockholders approved, the 2020 Employee Stock Purchase Plan (the "ESPP"), which became effective on March 11, 2020. The ESPP permits eligible employees who elect to participate, in six-month offering periods, to purchase shares of common stock through payroll deductions at a price equal to

85

% of the fair market value of the common stock on the first or last business day of each applicable six-month offering period, whichever is lower. Purchase dates under the ESPP occur on or about June 13 and December 13 each year.

On November 8, 2022, the Company's board of directors adopted, and on February 22, 2023, the Company's stockholders approved, an amendment to the ESPP to increase its share reserve. Following the Reverse Stock Split effected on February 23, 2023, the number of shares reserved for issuance under the ESPP is equal to

407,133

shares of the Company's common stock. The number of shares reserved shall be annually increased on the first day of each fiscal year, beginning with the fiscal year commencing on January 1, 2024 and continuing until, and including, the fiscal year commencing January 1, 2043, equal to the least of (i)

407,133

shares of the Company's common stock, (ii)

1

% of the number of shares of the Company's common stock outstanding on the first day of such fiscal year and (iii) an amount determined by the Company's board of directors. As of March 31, 2024,

809,890

shares of the Company's common stock remained available for issuance under the ESPP.

The Company did

no

t issue any shares under the ESPP during the three months ended March 31, 2024 and 2023. The Company had an outstanding liability of $

216,000
and $

53,000
at March 31, 2024 and December 31, 2023, respectively, which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets, for employee contributions to the ESPP for shares pending issuance at the end of the offering period. As of March 31, 2024, total stock-based compensation cost not yet recognized related to stock purchase rights under the ESPP was $

0.1
million, which is expected to be recognized over a weighted-average period of 0.2 years.

Stock options

The following table summarizes stock option activity:

	Stock Options Outstanding	Weighted-Average Exercise Price
Outstanding - January 1, 2024	5,817,339	$ 11.90
Options granted	2,089,517	14.86
Options exercised and vested	(151,116)	2.59
Options cancelled and forfeited	—	—
Outstanding - March 31, 2024	7,755,740	$ 12.88

As of March 31, 2024, total compensation cost not yet recognized related to unvested stock options was $

53.1
million, which is expected to be recognized over a weighted-average period of 3.0 years.

Restricted stock awards

Upon formation of Former Enliven in June 2019, Former Enliven issued approximately

3.0
million shares in restricted common stock to its founders. Additionally, between 2019 and 2020, Former Enliven issued a total of

197,262
shares of restricted stock to employees and consultants. As of March 31, 2024, total compensation cost not yet recognized for restricted stock awards was immaterial.

Restricted stock units

Restricted stock units ("RSUs") are valued at the market price of a share of the Company's common stock on the date of grant. The following table summarizes RSU activity:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested - January 1, 2024	78,505	$ 14.28
Granted	20,000	14.85

Vested	(2,688)	17.56
Forfeited	—	—
Unvested - March 31, 2024	95,817	$ 14.31

As of March 31, 2024, total compensation cost not yet recognized related to unvested RSUs was $ 1.3 million, which is expected to be recognized over a weighted-average period of 3.5 years.

Stock-based compensation expense

The allocation of stock-based compensation expense was as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 2,229	$ 492
General and administrative	2,286	1,770
Total stock-based compensation expense	$ 4,515	$ 2,262

The assumptions used in the Black-Scholes model to determine the fair value of stock option grants and stock purchase rights under the ESPP were as follows:

Stock Options	Three Months Ended March 31, 2024	2023
Expected term (years)	5.7 - 6.1	5.8
Expected volatility	84 %	83 %
Risk-free interest rate	4.0 % - 4.3 %	4.1 %
Expected dividend yield	— %	— %

ESPP	Three Months Ended March 31, 2024	2023
Expected term (years)	N/A	N/A
Expected volatility	N/A	N/A
Risk-free interest rate	N/A	N/A
Expected dividend yield	N/A	N/A

13. Net Loss Per Share

Basic and diluted net loss per common share were calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended March 31, 2024	2023
Numerator:		
Net loss	$ (22,738)	$ (14,724)
Denominator:		
Weighted-average common shares outstanding (including vested and unvested shares)	42,118,267	18,738,115
Less: weighted-average unvested common stock issued upon early exercise of common stock options	(68,244)	(149,069)
Less: weighted-average unvested restricted shares of common stock	(4,415)	(74,402)
Weighted-average shares used to compute net loss per common share, basic and diluted	42,045,608	18,514,644
Net loss per share, basic and diluted	$ (0.54)	$ (0.80)

Pre-Funded Warrants to purchase 1,071,505 shares of the Company's common stock were used in the calculation of the weighted-average common shares outstanding for the three months ended March 31, 2024.

The Company’s potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be antidilutive.

Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share is the same. The following potentially dilutive securities, presented on an as converted basis, were excluded from the calculation of net loss per share due to their anti-dilutive effect:

	As of March 31,	
	2024	2023
Stock options outstanding	7,755,740	3,890,266
Unvested restricted stock awards	2,493	59,339
Unvested restricted stock units	95,817	—
ESPP shares pending issuance	21,431	—
Total	7,875,481	3,949,605

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included elsewhere in this quarterly report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties, including those described in the section titled "Special Note Regarding Forward-Looking Statements." Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section titled "Risk factors" included elsewhere in this quarterly report on Form 10-Q.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery and development of small molecule inhibitors to help people with cancer not only live longer, but live better. We aim to address existing and emerging unmet needs with a precision oncology approach that improves survival and enhances overall well-being. Our discovery process combines deep insights in clinically validated biological targets and differentiated chemistry with the goal of designing therapies for unmet needs. By combining clinically validated targets and specific target product profiles with disciplined clinical trial design and regulatory strategy, we aim to develop drugs with an increased probability of clinical and commercial success. Clinically validated targets refers to biological targets that have demonstrated statistical significance on efficacy endpoints in published third-party clinical trials which we believe supports the development of our product candidates by increasing our probability of success. We have assembled a team of seasoned drug hunters with significant expertise in discovery and development of small molecule kinase inhibitors. Our team includes leading chemists who have been the primary or co-inventor of over 20 product candidates that have been advanced to clinical trials, including four FDA-approved products: Koselugo (selumetinib), Mektovi (binimetinib), Tukysa (tucatinib), and Retevmo (selpercatinib). We are currently advancing two parallel lead product candidates, ELVN-001 and ELVN-002, as well as pursuing several additional research stage opportunities that align with our development approach. We also nominated our third product candidate in the second quarter of 2023.

The following table summarizes our parallel lead product candidates:

Program	Target	Differentiation	Disease	Regimen	Discovery	IND-Enabling	Phase 1	Phase 2	Phase 3	Next Milestone	Milestone Expected
ELVN-001	BCR-ABL	Highly selective active site inhibitor w/activity against asciminib emergent mutations	CML	Monotherapy	monotherapy					Phase 1 Safety/Efficacy	2025
ELVN-002	HER2 & HER2 mutants	Irreversible, highly selective, CNS penetrant	NSCLC, other solid tumors	Monotherapy	monotherapy					Phase 1 Safety/Efficacy	2025
			HER2+ MBC and CRC	Combination	+ trastuzumab +/- chemotherapy					Phase 1a Safety/Efficacy	

Enliven Inc. (formerly, Enliven Therapeutics, Inc.) ("Former Enliven") was incorporated in the State of Delaware in June 2019, and we are headquartered in Boulder, Colorado. Since its inception, Former Enliven has devoted substantially all of its resources to research and development activities, including with respect to our breakpoint cluster region – Abelson ("BCR-ABL") and human epidermal growth factor receptor 2 ("HER2") programs and our other programs, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these activities.

We also do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical and preclinical testing, as well as for commercial manufacturing, should any of our product candidates obtain marketing approval. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel, while also enabling us to focus our expertise and resources on the development of our product candidates. In addition, we generally expect to rely on third parties for the manufacture of any companion diagnostics we may develop.

Former Enliven funded its operations primarily through private placements of its convertible preferred stock and sale of common stock, raising aggregate gross proceeds of $140.5 million from these private placements and an aggregate of $164.5 million in gross proceeds from the sale of common stock in the Former Enliven pre-closing financing (the "Financing Transaction"). In March 2024,

we sold in a private placement (the "Private Placement") common stock and pre-funded warrants to purchase shares of our common stock (the "Pre-Funded Warrants"), resulting in aggregate gross proceeds of $90.0 million. As of March 31, 2024, we had cash, cash equivalents and marketable securities of $320.5 million. Based on our current operating plan, our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operating expenses and capital expenditure requirements for at least the next 12 months from the date of the filing of this Form 10-Q.

As of March 31, 2024, we had an accumulated deficit of $177.2 million. We have incurred significant losses and negative cash flows from operations since inception, including net losses of $71.6 million and $37.7 million for the years ended December 31, 2023 and 2022, respectively, and $22.7 million for the three months ended March 31, 2024. We expect that our operating losses and negative operating cash flows will continue for the foreseeable future as we continue to develop our product candidates.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on a variety of factors including the timing and scope of our research and development activities. We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities as we:

- advance our BCR-ABL program through clinical development;
- advance our HER2 program through clinical development;
- advance our combination studies;
- advance any other product candidates through preclinical and clinical development;
- advance the development of our other small molecule research programs;
- expand our pipeline of product candidates through our own research and development efforts;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- develop a companion diagnostic;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates;
- contract to manufacture any approved product candidates;
- contract for supplies and drug product for use in potential combination studies;
- expand our clinical, scientific, management and administrative teams;
- maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know-how;
- implement operational, financial and management systems; and
- operate as a public company.

We do not have any products approved for commercial sale, and we have not generated any revenue from product sales or other sources. Our ability to generate product revenue sufficient to achieve and maintain profitability will depend upon the successful development and eventual commercialization of one or more of our product candidates, which we expect, if it ever occurs, will take many years. We will therefore require substantial additional capital to develop our product candidates and support our continuing operations. Accordingly, until such time that we can generate a sufficient amount of revenue from product sales, combination drug products, companion diagnostics or other sources, if ever, we expect to finance our operations through equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. However, we may be unable to raise additional capital from these sources on favorable terms, or at all. Our failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to delay, reduce or curtail our research, product development or future commercialization efforts. We may also be required to license rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. We cannot provide assurance that we will ever generate positive cash flow from operating activities.

The Merger and Financing Transaction

On October 13, 2022, we entered into an agreement and plan of merger ("Merger Agreement" and such transactions considered by the Merger Agreement, the "Merger") with Former Enliven and Iguana Merger Sub, Inc. ("Merger Sub"). Pursuant to the Merger Agreement, Merger Sub merged with and into Former Enliven, with Former Enliven continuing as our wholly owned subsidiary and the surviving corporation of the Merger. The Merger was intended to qualify for U.S. federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended (the "Code"). In the event that Former Enliven stockholders, including stockholders that participated in the Financing Transaction where an aggregate of $164.5 million of common stock of Former Enliven was purchased, were in "control" of us immediately after the Merger (within the meaning of Section 368(c) of the Code), the Merger was also intended to qualify as a non-taxable exchange of shares of Former Enliven common stock for shares of our common stock within the meaning of Section 351(a) of the Code.

At the closing of the Merger, (a) each outstanding share of Former Enliven common stock (including common stock issued upon the conversion of its preferred stock) was converted into the right to receive a number of shares of our common stock (after giving effect to our 1-for-4 reverse stock split of our common stock) equal to the exchange ratio per the Merger Agreement; and (b) each then outstanding Former Enliven stock option that had not previously been exercised prior to the closing of the Merger was assumed by us. Under the exchange ratio formula in the Merger Agreement, as of immediately after the Merger, Former Enliven's former stockholders owned approximately 84% of our outstanding shares of common stock, and our stockholders as of immediately prior to the Merger owned approximately 16% of our outstanding common stock.

Concurrently with the execution of the Merger Agreement, and in order to provide Former Enliven with additional capital for its development programs, prior to the closing of the Merger, certain new and current investors purchased an aggregate of $164.5 million of common stock of Former Enliven in the Financing Transaction. The Merger and the Financing Transaction were completed on February 23, 2023.

Macroeconomic and Geopolitical Developments

We are monitoring macroeconomic and geopolitical developments, such as inflation, instability in the banking and financial sector, tightening of the credit markets, the Russia-Ukraine and Israel-Hamas conflicts, and COVID-19, so that we may be prepared to react to new developments as they arise.

The extent of the impact of these developments on our business, operations and research and development timelines and plans remains uncertain and will depend on numerous factors, including the impact, if any, on our personnel, the responses of governmental entities, and the responses of third parties, such as contract research organizations ("CROs"), contract manufacturing organizations ("CMOs") and other third parties with whom we do business. Any prolonged material disruption to our employees or suppliers could adversely impact our development activities, financial condition and results of operations, including our ability to obtain financing. As a result of COVID-19, Pharmaron, a contract research organization that we use to conduct preclinical studies and clinical trials and provide us with active pharmaceutical ingredients ("APIs"), has previously experienced delays, which resulted in minor delays in our preclinical studies. For more information regarding the risks related to macroeconomic and geopolitical developments, see the section titled "*Risk Factors*" found elsewhere in this quarterly report on Form 10-Q.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue and we do not expect to generate any revenue from the sale of products or from other sources in the foreseeable future.

Operating Expenses

Research and Development

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal expenses incurred in connection with the discovery and development of our product candidates.

External expenses include:

- payments to third parties in connection with the development of our product candidates, including agreements with third parties such as CROs and consultants;

- the cost of manufacturing products for use in our clinical trials and preclinical studies, including payments to CMOs and consultants;
- the cost to acquire drug product for use in combination studies; and
- payments to third parties in connection with the preclinical development of our product candidates and any required companion diagnostics, including for outsourced professional scientific development services, consulting research and sponsored research.

Internal expenses include:

- personnel-related costs, including salaries, bonuses, related benefits and stock-based compensation expenses for employees engaged in research and development functions; and
- facilities-related expenses, depreciation, laboratory supplies, travel expenses and other allocated expenses.

We expense research and development expenses in the periods in which they are incurred. At any one time, we are working on multiple programs, and we do not track our research and development expenses on a program specific basis. Our internal resources, employees and infrastructure are not directly tied to any one research or drug discovery program and are typically deployed across multiple programs. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We utilize CROs for our research and development activities and CMOs for our manufacturing activities, and we do not have our own manufacturing facilities.

Product candidates in later stages of development generally have higher development costs than those in earlier stages. As a result, we expect that our research and development expenses will increase substantially over the next several years as we advance our product candidates through preclinical studies into and through clinical trials, continue to discover and develop additional product candidates, expand, maintain, protect and enforce our intellectual property portfolio, and hire additional research and development personnel.

The successful development of our product candidates is highly uncertain, and we do not believe it is possible at this time to accurately project the nature, timing and estimated costs of the efforts necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. To the extent our product candidates continue to advance into clinical trials, as well as advance into larger and later-stage clinical trials, our expenses will increase substantially and may become more variable. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates are subject to numerous uncertainties and will depend on a variety of factors, including:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we pursue;
- our ability to establish a sufficient safety profile with IND-enabling toxicology studies to enable clinical trials;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- per subject trial costs;
- the number and extent of trials required for regulatory approval;
- whether clinical trials with combination drugs are pursued;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects in clinical trials;
- the number of subjects that participate in the trials;
- the drop-out and discontinuation rate of subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the extent to which we encounter any serious adverse events in our clinical trials;

- the timing of receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals and post-marketing approval commitments from applicable regulatory authorities;
- the extent to which we establish collaborations, strategic partnerships or other strategic arrangements with third parties, if any, and the performance of any such third party;
- the timing and progress of development of any required companion diagnostic;
- our ability to acquire drug supply for any combination products and the cost of such drug supply;
- hiring and retaining research and development and clinical operations personnel;
- our arrangements with our CMOs and CROs;
- development and timely delivery of commercial-grade drug formulations that can be used in our planned clinical trials and for commercial launch;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work, particularly in light of the COVID-19 pandemic environment;
- the impact of any supply chain disruptions resulting from macroeconomic or geopolitical situations, including the COVID-19 pandemic, the Russia-Ukraine and Israel-Hamas conflicts; and
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights.

Any of these factors could significantly impact the costs, timing and viability associated with the development of our product candidates.

General and Administrative

General and administrative expenses consist of salaries, bonuses, related benefits and stock-based compensation expense for personnel in executive, finance and administrative functions; professional fees for legal, consulting, accounting and audit services; and travel expenses, technology costs and other allocated expenses. We expense general and administrative expenses in the periods in which they are incurred.

We expect that our general and administrative expenses will increase substantially over the next several years as we hire additional personnel to support the growth of our business. In addition, we expect to continue to incur significant expenses associated with being a public company, including expenses related to accounting, audit, legal, regulatory, public company reporting and compliance, director and officer insurance, investor and public relations, and other administrative and professional services.

Other Income (Expense), Net

Interest Income

Interest income primarily consists of interest earned on our cash, cash equivalents and marketable securities.

Results of Operations

Comparison of the three months ended March 31, 2024 and 2023

The following table summarizes our results of operations for the periods indicated:

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Operating expenses:		
Research and development	$ 19,970	$ 11,880
General and administrative	6,017	4,538
Total operating expenses	25,987	16,418
Loss from operations	(25,987)	(16,418)
Other income (expense), net	3,249	1,694
Net loss	$ (22,738)	$ (14,724)

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated:

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
External expenses	$ 14,034	$ 8,559
Internal expenses		
Employee related expenses	5,331	2,688
Facilities, laboratory supplies and other	605	633
Total internal expenses	5,936	3,321
Total research and development expenses	$ 19,970	$ 11,880

Research and development expenses were $20.0 million for the three months ended March 31, 2024 compared to $11.9 million for the three months ended March 31, 2023, an increase of $8.1 million. This increase was primarily due to increases in external research and development costs, consisting primarily of $3.4 million in clinical trial expenses, $1.9 million in contract manufacturing expenses and $0.6 million in consulting costs, partially offset by a decrease of $0.4 million in preclinical costs, as well as increases in internal research and development costs, consisting of $1.7 million in stock-based compensation and $0.9 million in salaries and benefits.

General and Administrative Expenses

General and administrative expenses were $6.0 million for the three months ended March 31, 2024 compared to $4.5 million for the three months ended March 31, 2023, an increase of $1.5 million. The increase was primarily due to an increase of $1.8 million in stock-based compensation primarily related to higher valuations on equity grants, $0.7 million in salaries and benefits and $0.3 million in other expenses, partially offset by a decrease of $1.3 million in stock-based compensation as a result of the acceleration of stock option vesting in connection with the Merger in February 2023.

Other Income (Expense), Net

Other income was $3.2 million for the three months ended March 31, 2024 compared to $1.7 million for the three months ended March 31, 2023. The increase was primarily related to higher interest income due to higher interest rates and higher investment balances.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales or other sources and have incurred significant operating losses and negative cash flows from our operations. Former Enliven funded its operations primarily through private placements of its

convertible preferred stock for gross proceeds of $140.5 million and sale of common stock in the Financing Transaction in February 2023 for gross proceeds of $164.5 million. In March 2024, we sold common stock and Pre-Funded Warrants in the Private Placement and received aggregate gross proceeds of $90.0 million. As of March 31, 2024, we had cash, cash equivalents and marketable securities of $320.5 million.

On June 23, 2023, we filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission (the "SEC"), which was declared effective by the SEC on July 3, 2023, which allows us to undertake various equity and debt offerings up to $400.0 million. On June 23, 2023, we also entered into an Open Market Sale Agreement℠ (the “Sales Agreement”) with Jefferies LLC (the "Sales Agent”), pursuant to which we may offer and sell shares of our common stock, from time to time, having an aggregate offering price of up to $200.0 million through the Sales Agent, in such share amounts as we may specify by notice to the Sales Agent, in accordance with the terms and conditions set forth in the Sales Agreement. Sales of our common stock made pursuant to the Sales Agreement, if any, will be made under our shelf registration statement on Form S-3. As of March 31, 2024, there have been no sales of common stock pursuant to the Sales Agreement.

Our primary uses of cash to date have been to fund our research and development activities, including with respect to our BCR-ABL and HER2 programs and our other programs, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these activities.

Future Capital Requirements

To date, we have not generated any revenue. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if, that will occur. Until such time as we can generate significant revenue from product sales, if ever, we will continue to require substantial additional capital to develop our product candidates and fund operations for the foreseeable future. We expect our expenses to increase significantly in connection with our ongoing activities as described in greater detail below. We are subject to all the risks incident in the development of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. We expect our expenses to increase significantly, as we:

- advance our BCR-ABL program through clinical development;
- advance our HER2 program through clinical development;
- advance our combination studies;
- advance any other product candidates through preclinical and clinical development;
- advance the development of our other small molecule research programs;
- expand our pipeline of product candidates through research and development efforts;
- expand our pipeline of research programs;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- develop a companion diagnostic assay;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates;
- contract to manufacture any approved product candidates;
- contract for supplies and drug product for use in potential combination trials;
- expand our clinical, scientific, management and administrative teams;
- maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know-how;
- implement operational, financial and management systems; and
- operate as a public company.

In order to complete the development of our product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional capital. Accordingly, until such time that we can generate a sufficient amount of revenue from product sales or other sources, if ever, we expect to seek to raise any necessary additional capital through equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. To the extent that we raise additional capital through equity financings or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments or engage in merger, consolidation, licensing or asset sale transactions. If we raise capital through collaborations, partnerships and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional capital from these sources on favorable terms, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States. Our failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to delay, reduce or curtail our research, product development or future commercialization efforts. We may also be required to license rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. We cannot provide assurance that we will ever generate positive cash flow from operating activities.

We expect that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date of this filing. Former Enliven received gross proceeds of $164.5 million from the Financing Transaction in February 2023, and we received gross proceeds of $90.0 million from the Private Placement in March 2024. We expect to continue to incur costs associated with operating as a public company. In addition, we anticipate that we will need substantial additional funding in connection with our continuing operations. We have based our projections of operating capital requirements on our current operating plan, which includes several assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount and timing of our capital requirements. Our future funding requirements will depend on many factors, including:

- the scope, timing, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the scope, timing, progress, results and costs of researching and developing other product candidates that we may pursue;
- the cost of research and development to expand our pipeline of research programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- the cost of developing a companion diagnostic;
- the cost of acquiring drug product for any combination studies;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the cost and timing of attracting, hiring and retaining skilled personnel to support our operations and continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- our ability to establish, maintain, and derive value from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies, if any; and
- the costs associated with operating as a public company.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional capital to meet the capital requirements associated with such operating plans.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (23,361)	$ (20,844)
Net cash used in investing activities	(17,885)	(31)
Net cash provided by financing activities	90,270	237,441
Net increase in cash, cash equivalents, and restricted cash	$ 49,024	$ 216,566

Cash Flows from Operating Activities

Net cash used in operating activities during the three months ended March 31, 2024 was $23.4 million. This consisted primarily of a net loss of $22.7 million, net cash outflows from changes in our operating assets and liabilities of $4.6 million (primarily due to an increase in prepaids and other assets and a net decrease in accounts payable and accrued expenses and other liabilities) and non-cash amortization of premiums and discounts on marketable securities of $0.7 million, partially offset by non-cash charges for stock-based compensation of $4.5 million and other non-cash charges of $0.1 million.

Net cash used in operating activities during the three months ended March 31, 2023 was $20.8 million. This consisted primarily of a net loss of $14.7 million and net cash outflows from changes in our operating assets and liabilities of $8.4 million (primarily due to an increase in prepaids and other assets and a net decrease in accounts payable and accrued expenses and other liabilities), partially offset by non-cash charges for stock-based compensation of $2.3 million.

Cash Flows from Investing Activities

Net cash used in investing activities during the three months ended March 31, 2024 was $17.9 million. This consisted primarily of cash used to purchase marketable securities of $56.8 million, partially offset by proceeds from maturities of marketable securities of $38.9 million.

Net cash used in investing activities during the three months ended March 31, 2023 was $31,000. This consisted primarily of cash used to purchase property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities during the three months ended March 31, 2024 was $90.3 million. This consisted primarily of net proceeds from the sale of shares of our common stock and Pre-Funded Warrants in the Private Placement of $90.0 million and proceeds from the exercise of stock options of $0.3 million.

Net cash provided by financing activities during the three months ended March 31, 2023 was $237.4 million. This consisted primarily of net proceeds from the sale of shares of our common stock in the Financing Transaction of $162.9 million, net cash acquired in connection with the reverse recapitalization of $74.4 million, and proceeds from the exercise of stock options of $0.1 million.

Contractual Obligations and Commitments

We sublease certain office and laboratory space in Boulder, Colorado, under which the sublease was scheduled to expire in December 2021. We amended the lease in March 2021 and in April 2022 to expand its size and extend its expiration date to December 2024.

The following table summarizes our contractual obligations and commitments as of March 31, 2024 (in thousands):

	Total	Payments Due by Period Remainder of 2024	Thereafter
Operating lease obligations	$ 256	$ 256	$ —

We have also entered into agreements in the normal course of business with certain vendors for the provision of goods and services, which includes manufacturing services with CMOs and development services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. These obligations and commitments are not separately presented.

Off-Balance Sheet Arrangements

We currently do not have, and did not have during the periods presented, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our 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 a periodic basis. Our actual results may differ from these estimates. As of March 31, 2024, there have been no material changes to our critical accounting policies and estimates from those disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Judgments and Estimates,” included in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 14, 2024.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial condition and results of operations is disclosed in Note 2 to our unaudited condensed consolidated financial statements appearing elsewhere in this quarterly report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

As of March 31, 2024, our cash, cash equivalents and marketable securities consisted primarily of U.S. Treasury securities and U.S. Treasury-backed money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term maturities of our investments, we believe a hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would not have had a material impact on our financial results.

As of March 31, 2024, we had no debt outstanding and are therefore not exposed to interest rate risk with respect to debt.

Foreign Currency Exchange Risk

Our primary operations are transacted in U.S. dollars. However, we have entered into a limited number of contracts with vendors for research and development services that are denominated in foreign currencies, including euros/British pounds. We could be subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. We do not currently engage in any hedging activity to reduce our potential exposure to currency fluctuations, although we may choose to do so in the future. We believe a hypothetical 100 basis point increase or decrease in foreign exchange rates during any of the periods presented would not have had a material impact on our financial condition or results of operations.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to management including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. As of March 31, 2024, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of March 31, 2024.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings arising in the ordinary course of our business. We are not currently a party to any material litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors. The information set forth in Note 9. Commitments and Contingencies—Litigation to our unaudited condensed consolidated financial statements included in this quarterly report on Form 10-Q is incorporated herein by reference.

Item 1A. Risk Factors.

Risk factors

You should carefully consider the risks described below, as well as the other information in this quarterly report on Form 10-Q, including our unaudited condensed consolidated financial statements and related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our other public filings in evaluating our business. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

Risk Factor Summary

We are early in our development efforts, with a limited operating history, and we have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and future viability.

- We have incurred significant net losses and we expect to continue to incur significant net losses for the foreseeable future.
- We have never generated revenue from product sales and we may never achieve or maintain profitability.
- We are substantially dependent on ELVN-001 and ELVN-002. If we are unable to advance ELVN-001 or ELVN-002 through clinical development, obtain regulatory approval and ultimately commercialize such product candidates, or experience significant delays in doing so, our business will be materially harmed.
- The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, European Medicines Agency ("EMA") or other comparable foreign regulatory authorities.
- We have limited resources and are currently focusing our efforts on ELVN-001 and ELVN-002 for development in particular indications and advancing our other research programs. As a result, we may fail to capitalize on programs, product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- Our prospects depend in large part upon developing and commercializing ELVN-001 and ELVN-002 and discovering, developing and commercializing product candidates from our other research programs, and failure to successfully identify, develop and commercialize additional product candidates could impair our ability to grow.
- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval of our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- The market price of our common stock may be volatile and may drop.
- We will need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital on favorable terms, on a timely basis or at all, we would be forced to delay,

reduce or eliminate our product development and clinical programs and may not have the capital required to otherwise operate our business.

• We have incurred and will continue to incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

Risks Related to Our Limited Operating History, Financial Position and Need for Additional Capital

We are early in our development efforts, with a limited operating history, and we have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and future viability.

We are a clinical stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects.

Former Enliven commenced operations in June 2019, has never completed a clinical trial, has no products approved for commercial sale and has never generated any revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We are devoting substantially all of our resources to developing ELVN-001 and ELVN-002, research and development activities, clinical trial activities, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. We are currently evaluating ELVN-001 in a Phase 1 clinical trial in adults with CML, and we are evaluating ELVN-002 in a Phase 1 clinical trial in adults with solid tumors with HER2 alterations. We received FDA clearance and activated the first site in the first quarter of 2024 for an additional Phase 1 trial evaluating ELVN-002 in combination with trastuzumab with and without chemotherapy in MBC and CRC with overexpressed or amplified HER2. We have nominated a development candidate for our third program and have completed IND-enabling studies for that product candidate. We have not initiated clinical trials for any other product candidate.

In April 2024, we announced positive proof of concept data from the Phase 1 clinical trial evaluating ELVN-001 in patients with chronic myeloid leukemia (“CML”) who are relapsed, refractory, or intolerant to available tyrosine kinase inhibitors (“TKIs”). However, we have not yet demonstrated our ability to complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, develop a companion diagnostic, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for investors to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. We also expect that, as we advance our product candidates, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses, have not generated any revenue to date and have financed our operations principally through private placements of our preferred stock. Our net loss was $22.7 million for the three months ended March 31, 2024. As of March 31, 2024, we had an accumulated deficit of $177.2 million. We are still in the very early stages of development of our product candidates and have not yet completed any clinical trials. As a result, we expect that it will be many years, if ever, before we have commercialized a product and can generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. 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. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our stock.

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

We have never generated any revenue from commercial product sales. To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential, which will require us to be successful in a range of challenging activities. These activities can include completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products that are approved and satisfying any post-marketing requirements. We do not anticipate generating any revenue from product sales for many years, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives, including:

- successful and timely completion of clinical development of ELVN-001, ELVN-002, including development of any combination drug products, and any other product candidates, preclinical and clinical development of other research programs and any other future programs, and/or development of a companion diagnostic, if required for regulatory approval;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development of ELVN-001, ELVN-002 and any other programs;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- developing an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate products and services, in both amount and quality, to support our combination studies, clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

Any changes in the manufacturing process, suppliers, or facilities will require further comparability analysis and approval by the FDA before implementation, which could delay our clinical trials and product candidate development, and could require additional clinical trials, including bridging studies, to demonstrate consistent and continued safety and efficacy. If we pursue alternative tablet formulations or other changes to any of our product candidates, the FDA and other regulatory authorities may require additional studies, including bridging studies, which may significantly delay our clinical trial timelines and regulatory approval.

We have not submitted a New Drug Application ("NDA") to the FDA or similar approval filings to a comparable foreign regulatory authority for any product candidate. An NDA or other relevant regulatory filing must include extensive nonclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product candidate. We cannot be certain that our current or future product candidates will be successful in clinical trials or receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates or companion diagnostics, as applicable, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we receive regulatory approval and have commercial rights, the availability of competitive therapies and whether there are sufficient levels of reimbursement and adoption by physicians.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

We are very early in our development efforts. In addition, we are substantially dependent on ELVN-001 and ELVN-002. If we are unable to advance ELVN-001 or ELVN-002 through clinical development, obtain regulatory approval and ultimately commercialize such product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts. We are currently evaluating ELVN-001 in a Phase 1 clinical trial in adults with CML, and we are evaluating ELVN-002 in a Phase 1 clinical trial in adults with solid tumors with HER2 alterations. We received FDA clearance and activated the first site in the first quarter of 2024 for an additional Phase 1 trial evaluating ELVN-002 in combination with trastuzumab with and without chemotherapy in MBC and CRC with overexpressed or amplified HER2. We have nominated a development candidate for our third program and have completed IND-enabling studies for that product candidate. We have not initiated clinical trials for any other product candidate and we may experience unexpected or adverse results in the future. We will be required to demonstrate thorough, adequate and well-controlled clinical trials that our product candidates are safe and effective, with a favorable benefit-risk profile, for use in their target indications before we can seek regulatory approvals for their commercial sale. Our initial clinical trials will begin with relatively small cohorts before expanding in size in subsequent cohorts. If safety issues arise in an early cohort, we may be delayed or prevented from subsequently expanding into larger trial cohorts. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of ELVN-001 and ELVN-002, including the development of any combination drug products or companion diagnostics. We are not permitted to market or promote any product candidate before it receives marketing approval from the FDA, EMA or any comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Preclinical and clinical testing is expensive and can take many years to complete, and our outcome is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in early stages of developments, there is a high risk of failure and we may never succeed in developing marketable products.

The results of preclinical studies may not be predictive of the results of clinical trials of our product candidates. Moreover, the results of early clinical trials may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be safe or effective in subsequent clinical trials. Favorable results from certain animal studies may not accurately predict the results of other animal studies or of human trials, due to the inherent biologic differences in species, the differences between testing conditions in animal studies and human trials, and the particular goals, purposes, and designs of the relevant studies and trials.

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Likewise, early, smaller-scale clinical trials may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials. 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 drugs. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product

candidates that commence preclinical studies and clinical trials are never approved as products. The development of our product candidates and our stock price may also be impacted by inferences, whether correct or not, that are drawn between the success or failure of preclinical studies or clinical trials of our competitors or other companies in the biopharmaceutical industry, in addition to our own preclinical studies and clinical trials.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

Any preclinical studies or clinical trials that we conduct may not demonstrate the safety and efficacy necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants.

We do not know whether any preclinical studies or clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates.

We have limited resources and are currently focusing our efforts on ELVN-001 and ELVN-002 for development in particular indications and advancing our other research programs. As a result, we may fail to capitalize on programs, product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We are currently focusing our resources and efforts on ELVN-001, ELVN-002 and advancing our other research programs. Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forgo or delay pursuit of opportunities for other indications or with other product candidates that may 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 activities for ELVN-001, ELVN-002 and our other research programs, including the development of any combination drug products or companion diagnostics, may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target markets for ELVN-001, ELVN-002 and our other research programs, or the product candidates we are currently developing in these programs, we may relinquish valuable rights to our product candidates or programs through collaborations, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or program.

Our prospects depend in large part upon developing and commercializing ELVN-001 and ELVN-002 and discovering, developing and commercializing product candidates from our other research programs, and failure to successfully identify, develop and commercialize additional product candidates could impair our ability to grow.

Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates including ELVN-001, ELVN-002 and product candidates from our research programs, including the development of any combination drug products or companion diagnostics. A product candidate can unexpectedly fail at any stage of development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of ELVN-001, ELVN-002 and other product candidates we may develop will depend on many factors, including the following:

- successful and timely completion of preclinical studies, including generating sufficient data to support the initiation or continuation of preclinical studies and clinical trials, including data that demonstrates improved efficacy, safety, and patient convenience compared to our competitors' products;
- successful development of combination drug products;
- successful development of a companion diagnostic, if required for regulatory approval of any product;
- obtaining institutional review board ("IRB") approval at each clinical trial site;
- approval of INDs for our planned clinical trials and future clinical trials;
- the timely manufacture of sufficient quantities of a product candidate for use in clinical trials;
- successful initiation and completion of clinical trials;
- successful and timely patient selection and enrollment in and completion of clinical trials;
- maintaining and establishing relationships with CROs and clinical sites for the clinical development of our product candidates both in the United States and internationally;
- the frequency and severity of adverse events in clinical trials;
- demonstrating efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development, combination studies, and, if approved, commercialization of our product candidates;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- the protection of our rights in our intellectual property portfolio;
- the successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of preclinical and clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to 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 from our lead programs, which would materially harm our business. If we do not receive marketing approvals for such product candidates, we may not be able to continue our operations.

Although a substantial amount of our efforts will focus on the continued preclinical and clinical testing and potential approval of our product candidates in our current pipeline, we expect to continue to innovate and potentially expand our portfolio. Research programs to identify product candidates may require substantial additional technical, financial and human resources, whether or not any new potential product candidates are ultimately identified. Our success may depend in part upon our ability to identify, select and develop promising product candidates and therapeutics. We may expend resources and ultimately fail to discover and generate additional product candidates suitable for further development. Even if we successfully advance any product candidates into preclinical and clinical development, their success will be subject to all of the preclinical, clinical, regulatory and commercial risks

described elsewhere in this section. All product candidates are prone to risks of failure typical of biotechnology product development, including the possibility that a product candidate may not be suitable for clinical development as a result of its harmful side effects, limited efficacy or other characteristics indicating that it is unlikely to receive approval by the FDA, the EMA and other comparable foreign regulatory authorities and achieve market acceptance. If we do not successfully develop and commercialize ELVN-001 or ELVN-002, or successfully identify, develop and commercialize new product candidates, our business, prospects, financial condition and results of operations could be adversely affected.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. We do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any jurisdiction. Our product candidates may fail to demonstrate efficacy in humans, and particularly across tumor types. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk we face is the possibility that none of our product candidates under development will successfully gain market approval from the FDA, EMA or other comparable foreign regulatory authorities, resulting in us being unable to derive any commercial revenue from them after investing significant amounts of capital in their development.

If the results of our ongoing or future preclinical studies and future clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants.

As is typically the case with oncology drugs, there have been adverse events associated with the use of our product candidates and there could be adverse events caused by our product candidates in the future. Results of our future trials could reveal a high and unacceptable severity and prevalence of side effects, toxicities or adverse events when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences. For example, our trials could be suspended or terminated and the FDA, EMA or comparable foreign regulatory authorities or an IRB could order us to suspend clinical trials, cease further development of or deny approval of our product candidates for any or all targeted indications. This could require us to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects have resulted, and could result in additional patients dropping out of our trials, and could affect patient recruitment and the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

In addition, our product candidates may be used in populations for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, our product candidates may be studied in combination with other therapies, which may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients to be enrolled in our future clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such trials for non-treatment related reasons.

Further, our product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed, or if our product candidates have characteristics that are unexpected, we may need to abandon our development or limit development to more narrow indications or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to the tolerability of our products versus other therapies. Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label including "black box" warnings, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval of our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

Our product candidates are and will continue to be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be approved for marketing.

Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. For example, the FDA's Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in early clinical settings, among other goals. How the FDA plans to implement these goals and their impact on specific clinical programs and the industry are unclear. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product candidate's commercial potential. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for our proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, EMA or other comparable regulatory authorities may fail to approve companion diagnostic tests required for our product candidates; and
- the approval policies or regulations of the FDA, EMA or other comparable 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 the results of clinical trials, may result in us failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

In addition, the FDA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. Additionally, if the Supreme Court reverses or curtails the *Chevron* doctrine, which gives deference to regulatory agencies in litigation against the FDA and other agencies, more companies may bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could delay the FDA's review of our marketing applications.

If we are required by the FDA or comparable regulatory authorities to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates or a group of therapeutic products, and we do not obtain or we face delays in obtaining approval of a diagnostic test, we will not be able to commercialize the product candidate and our ability to generate revenue will be materially impaired.

We are a precision oncology company. If we are required by the FDA or comparable regulatory authorities to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates, such companion diagnostic test would be used during our more advanced phase clinical trials as well as in connection with the commercialization of our product candidates. To be successful in developing and commercializing product candidates in combination with these companion diagnostics, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared at the same time the product candidate is approved.

The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express certain biomarkers or the specific genomic alteration that the companion diagnostic was developed to detect. The FDA or a comparable regulatory authority may require approval of a companion diagnostic for any of our product candidates, whether before or concurrently with approval of the product candidate. We and/or future collaborators may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of our related product candidates. Further, in April 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. In June 2023, the FDA announced a new voluntary pilot program through which drug manufactures can provide to the FDA the diagnostic test performance information used to enroll patients into clinical trials for drug approval. Based on assessment of the performance information, the FDA will publish the minimum performance

characteristics recommended for similar tests that may be used to select patients for treatment with the approved drug to help laboratories identify specific biomarkers for their development of laboratory-developed tests ("LDTs") and to ensure more consistent performance of these tests for drug selection and improved cancer patient care. In September 2023, the FDA issued a proposed rule that, if finalized, will amend the FDA's regulations to make explicit that in vitro diagnostics ("IVDs") are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory, and will phase out its enforcement discretion for LDTs. These future issuances from the FDA and other regulatory developments in this area may impact our companion diagnostic development and strategy in connection with our product candidates and result in delays in regulatory approval. We may be required to conduct additional clinical trials to support a broader claim.

Additionally, we may rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected, our product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of our product candidates that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of product candidates or our relationship with such diagnostic company may otherwise terminate. In addition, such diagnostic company may not agree to commercialize the companion diagnostic test in all the countries in which we may sell our product candidates. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

We have limited experience as a company in designing and conducting clinical trials.

The design and implementation of clinical trials is a complex process. We have limited experience as a company in designing and conducting clinical trials. We are currently evaluating ELVN-001 in a Phase 1 clinical trial in adults with CML, and we are evaluating ELVN-002 in a Phase 1 clinical trial in adults with solid tumors with HER2 alterations. We received FDA clearance and activated the first site in the first quarter of 2024 for an additional Phase 1 trial evaluating ELVN-002 in combination with trastuzumab with and without chemotherapy in MBC and CRC with overexpressed or amplified HER2. We have nominated a development candidate for our third program and have completed IND-enabling studies for that product candidate. However, we have not initiated clinical trials for any other product candidate and we may experience unexpected or adverse results in the future. In part because of this lack of experience as a company and our limited infrastructure, we cannot be certain that our ongoing and planned preclinical studies and clinical trials will be completed on time, that we will successfully or cost-effectively design and implement clinical trials that achieve the desired clinical endpoints efficiently, or at all. Large-scale clinical trials would require significant additional financial and management resources and reliance on CROs and consultants. Relying on third-party clinical investigators, CROs and consultants may force us to encounter delays that are outside of our control. We may be unable to identify and contract with sufficient investigators, CROs and consultants on a timely basis or at all. There can be no assurance that we will be able to negotiate and enter into any necessary services agreement with CROs on terms that are acceptable to it on a timely basis or at all.

Any delays in the commencement or completion, or termination or suspension of our planned or future clinical trials could result in increased costs, delay or limit our ability to generate revenue and adversely affect our commercial prospects. We may not be able to file INDs to commence clinical trials on the timelines we expect, and even if we are able to, the FDA, EMA or other comparable foreign regulatory authorities may not permit us to proceed.

Before we can initiate clinical trials of a product candidate in any indication, we must submit the results of preclinical studies to the FDA, EMA or other comparable foreign regulatory authorities along with other information, including information about the product candidate's chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission under which we must receive authorization to proceed with clinical development. Although we have received clearance

of the IND for ELVN-001 and ELVN-002, the FDA, EMA or other comparable foreign regulatory authorities may require us to conduct additional studies before they allow us to initiate additional clinical trials or at any time during clinical testing, clinical trial authorization or comparable application, which may lead to additional delays and increase the costs of our preclinical development programs. Before obtaining marketing approval from the FDA of ELVN-001, ELVN-002 or any other programs, we must conduct extensive clinical trials to demonstrate safety and efficacy. Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, we expect to rely in part on preclinical, clinical and quality data generated by our CROs and other third parties for regulatory submissions for our product candidates. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. We could encounter delays because we may need to relocate our corporate headquarters, which includes office and laboratory space. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase. We may not be able to file INDs for future product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if the FDA agrees with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that it will not change its requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our planned clinical trials may prevent us from initiating or completing our clinical trials or commercializing our product candidates on a timely basis, if at all.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or independent ethics committees of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or foreign regulatory authorities. Such authorities may impose such a suspension or termination 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 or foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse events, failure to demonstrate a benefit from using a pharmaceutical, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. For example, the Clinical Trials Regulation EU No 536/2014 entered into application on January 31, 2022, which aims to harmonize and streamline clinical trial authorization, simplify adverse event reporting procedures, and increase clinical trial transparency. Changes to regulatory requirements or the implementation of new requirements can increase the costs of compliance and expose us to great liabilities. Amendments may require us to resubmit our clinical trial protocols to IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial. From time to time, certain of our current or future scientific advisors or consultants who receive compensation from us may become investigators for our future clinical trials. Under certain circumstances, we may be required to report some of these relationships to the FDA.

Although we expect any such relationships to be within the FDA's guidelines, the FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates. If we experience delays in the completion of, or termination of, any clinical trial of any product candidate, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues which may harm our business, financial condition, results of operations and prospects significantly.

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

From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies and clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, we may report responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. 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 and carefully evaluate all data. As a result, the topline results

that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or trial is typically selected from a more extensive amount of available information. Investors may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

If we experience delays or difficulties in the enrollment or maintenance of participants that meet the protocol criteria in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue 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 to such trials' conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited, and we have experienced minor delays in enrollment. Because there are effective, approved drugs and/or ongoing clinical trials being conducted for CML and for solid tumors with HER2 alterations, it may make it difficult for us to enroll patients in our trials for the same indications. For example, CML patient enrollment could have been and will likely be affected by the recent approval of asciminib as well as our competitors that have ongoing clinical trials for programs that are under development for the same indications as our product candidates because patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' programs. Similarly, patient enrollment for our clinical trials directed to solid tumors with HER2 alterations may be impacted by competing therapeutics approved for NSCLC, MBC or CRC or for tumors with the same genetic mutation as the indications we may pursue for our product candidates, as well as clinical trials of other investigational products that may compete with our trials. Additionally, the CML patient population is relatively small and certain clinical trials for future product candidates may be focused on indications with relatively small patient populations, which may further limit enrollment of eligible patients or may result in slower enrollment than we anticipate.

In our ELVN-001 and ELVN-002 programs, we utilize genomic profiling of patients' tumors to identify suitable patients for recruitment into our clinical trials. We cannot be certain (1) how many patients will have the requisite alterations for inclusion in our clinical trials, (2) that the number of patients enrolled in each program will suffice for regulatory approval or (3) whether each specific BCR-ABL or HER2 mutation will be included in the approved drug label. If our strategies for patient identification and enrollment prove unsuccessful, we may have difficulty enrolling or maintaining patients appropriate for our product candidates.

Patient enrollment for our current or any future clinical trials has been and may continue to be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol, including biomarker-driven identification and/or certain highly specific criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have biomarker-driven patient eligibility criteria;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or other product candidates being investigated for the indications we are investigating;

- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- treatment of patients at local facilities rather than central facilities;
- proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. We intend to establish clinical trial sites in Israel, which may face enrollment, retention, operational or other difficulties due to conflicts within the region, including, for example, difficulties importing clinical trial drug through Israeli customs, difficulties with patient enrollment, or difficulties with patients or medical personnel accessing appropriate medical facilities. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

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

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. In particular, precision oncology is a very competitive space and we have chosen to prioritize addressing well-validated biological targets, and therefore we expect to face competition from existing products and products in development for each of our product candidates. While we believe that our technology, the expertise of our team, and our development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing product candidates in our field before we do.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects, and are more convenient or less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we can, which could result in our competitors establishing a strong market position before we are able to enter the market or could otherwise make our development more complicated. We believe the key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and patient convenience. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness.

There are currently six BCR-ABL TKIs approved for use in CML by the FDA: Novartis AG's Gleevec (imatinib), Tasigna (nilotinib), Scemblix (asciminib), Bristol Myers Squibb's Sprycel (dasatinib), Pfizer's Bosulif (bosutinib), and Takeda's Iclusig (ponatinib), which are more fully described in the Business section of our Annual Report on Form 10-K filed with the SEC on March 14, 2024.

There are no approved TKIs for HER2 mutant NSCLC by the FDA. Enhertu (fam-trastuzumab deruxtecan), an antibody drug conjugate, marketed by AstraZeneca and Daiichi-Sankyo, received accelerated approval from the FDA for this patient population in August 2022. Most of the investigational TKIs for this population are all dual EGFR and HER2 inhibitors such as Spectrum's poziotinib, Takeda's mobocertinib, Black Diamond's BDTX-189 and Jiangsu HengRui Medicine Co., Ltd's pyrotinib. Pyrotinib is being investigated in a Phase 3 pivotal trial. Bayer received FDA Breakthrough Therapy designation and increased their trial's sample size to advance BAY2927088 in patients with HER2 mutant NSCLC that have progressed on a prior systemic agent with no other approved treatment. Boehringer Ingelheim initiated a pivotal study with Zongertinib (BI-1810631), a HER2-specific TKI, in newly diagnosed patients with HER2 mutant NSCLC. Other TKIs are in late-stage research for HER2 mutant NSCLC including Nuvalent's NVL-330 and Cogent Biosciences' CGT4255.

For HER2 amplified and overexpressing tumors, such as BRC, there are several FDA-approved antibodies, antibody drug conjugates, and TKIs. For example, Genentech's Herceptin (trastuzumab) and Perjeta (pertuzumab) are approved HER2-antibodies. Approved HER2-antibody drug conjugates include Genentech's Kadcyla (ado-trastuzumab emtansine) and Daiichi Sankyo's Enhertu (fam-trastuzumab deruxtecan). Approved TKIs for HER2 positive BRC include Puma's Nerlynx (neratinib), Novartis AG's Tykerb (lapatinib), and Seagen's Tukysa (tucatinib). Several of these drugs are approved for other HER2-driven indications such as gastric and colorectal cancer. The competitive landscape for HER2 positive breast cancer may become more competitive as multiple novel monotherapy and combinations are presently being evaluated in early clinical trials. Roche's ZN-A-1041/RG6596 and Iambic Therapeutics' IAM1363 are HER2 selective TKIs in early-stage development for HER2-altered cancers. Furthermore, Enhertu received accelerated approval from the FDA for HER2 positive (IHC3+) metastatic solid tumors.

Finally, there are numerous other investigational therapies, spanning many modalities, that are being evaluated preclinically and in clinical trials for various HER2-altered cancers.

Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, as well as sophisticated quality assurance and quality control procedures. From time to time, we have experienced, and may in the future experience, deviations in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, which have resulted and may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

If our third-party manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. For example, our plans to change the formulation, e.g., to a tablet form, for one or more of our product candidates during the course of our clinical trials could increase our costs and delay regulatory approval. Such changes carry the risk that they will not achieve these intended objectives.

Any of these changes could cause our product candidates to perform differently and affect the results of clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue. If we pursue alternative tablet formulations or other changes to any of our product candidates, the FDA and other regulatory authorities may require additional studies, including bridging studies, which may significantly delay our clinical trial timelines and regulatory approval.

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a risk evaluation and mitigation strategy ("REMS"), if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- the availability of an approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and undergo required diagnostic screening to determine treatment eligibility and of physicians to prescribe these therapies and diagnostic tests;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

If any of our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

The market opportunities for any product candidates we develop, if approved, may be limited to certain smaller patient subsets and may be smaller than we estimate them to be.

When cancer is detected early (referred to as localized disease), conventional treatments which include chemotherapy, hormone therapy, surgery and radiation therapy and/or selected targeted therapies may be adequate to cure the patient in many cases. However, once cancer has spread to other areas (advanced or metastatic disease), cancer treatments may not be sufficient to provide a cure but often can significantly prolong life without curing the cancer. First-line (“1L”) therapies designate treatments that are initially administered to patients with advanced or metastatic disease, while second-line (“2L”) and third or later line therapies are administered to patients when the prior therapies lose their effectiveness. The FDA, EMA and other comparable foreign regulatory bodies often approve cancer therapies for a particular line of treatment. Typically, drug approvals are initially granted for use in later lines of treatment, but with additional evidence of significant efficacy from clinical trials, biopharmaceutical companies can successfully seek and gain approval for use in earlier lines of treatment.

We plan to initially seek approval of our product candidates in most instances at least as a second-or third-line therapy, for use in patients with advanced or metastatic cancer where at least one prior therapy has limited clinical benefit or has lost its effectiveness. For those product candidates that prove to be sufficiently safe and effective, if any, we would expect to seek approval as a 2L

therapy and potentially ultimately as a 1L therapy. There is no guarantee that our product candidates, even if approved as a second, third or subsequent line of therapy would be approved for an earlier line of therapy, and prior to any such approvals we may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the cancers that we are targeting. The potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Consequently, even if our product candidates are approved, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type. Even if we obtain significant market share for our products, if approved, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

We face risks related to health epidemics and other outbreaks, such as COVID-19, which could significantly disrupt our operations or otherwise result in material adverse impacts to us.

Our business could be adversely impacted by the effects of health epidemics and other outbreaks, including:

- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- difficulties interpreting data from our clinical trials due to the possible effects of health epidemics or other outbreaks on patients;
- interruption of key preclinical and clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or due to restricted or limited operations of the CROs conducting such studies;
- interruption or delays in the operations of the FDA, EMA or other regulatory authorities, which may impact review and approval timelines;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials;
- limitations in resources that would otherwise be focused on the conduct of our business, our preclinical studies or our clinical trials, including because of sickness or the desire to avoid contact with large groups of people or as a result of government-imposed “shelter in place” or similar working restrictions;
- delays in receiving approval from regulatory authorities to initiate our clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global freight and shipping that may affect the transport of clinical trial materials, such as investigational drug product to be used in our clinical trials;
- changes in regulations as part of a response to health epidemics or other outbreaks which may require us to change the ways in which our clinical trials are to be conducted, or to discontinue the clinical trials altogether, or which may result in unexpected costs;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA, EMA or other regulatory authorities to accept data from clinical trials in affected geographies outside of their respective jurisdictions.

The extent to which COVID-19, including emergence of new variants or resurgence in COVID-19 cases, or any other health epidemic, impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of a particular virus and its variants and the actions to contain it or treat its impact, among others. There can be no assurance that we will be able to avoid a material impact on our business, financial condition

and operating results from the spread of COVID-19 or its consequences, including disruption to our business and downturns in business sentiment generally or in our industry.

To the extent a health epidemic or other outbreak adversely affects our business, financial condition and operating results, it may also have the effect of heightening many of the risks described in this section.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of such product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

As federal and state governments implement additional health care cost containment measures, including measures to lower prescription drug pricing, we cannot be sure that our products, if approved, will be covered by private or public payors, and if covered, whether the reimbursement will be adequate or competitive with other marketed products. Any actions by federal and state governments, such as the Inflation Reduction Act of 2022 ("IRA"), and health plans aimed at putting additional downward pressure on pharmaceutical pricing and health care costs could negatively impact coverage and reimbursement for our product candidates if approved, our revenue, and our ability to compete with other marketed products and to recoup the costs of our research and development. For further discussion, see " — *We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations*."

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. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for our product candidates, if approved.

Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union ("EU"), medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. 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. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to advancing additional product candidates into clinical trials or marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is expensive and may increase over time. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

We may develop our current or future product candidates in combination with other therapies, which would expose us to additional risks.

As part of our development strategy, we are seeking strategic collaborations to develop our current or future product candidates in combination with one or more currently approved cancer therapies or therapies in development. Even if any of our current or future product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

We or our future third party collaborators may also evaluate our current or future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA, EMA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or future product candidates, we may be unable to obtain approval of or successfully market any one or all of the current or future product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have never commercialized a product candidate as a company before and currently lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate as a company. We may license certain rights with respect to our product candidates to collaborators, and, if so, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our approved product candidates, ensuring regulatory compliance of our company, employees and third parties under applicable healthcare laws, and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We currently conduct our clinical trial for ELVN-001 in the United States, Australia, France, Germany, South Korea, and Spain. In the future, we may conduct clinical trials for ELVN-001 in other countries, including but not limited to Poland, Italy, Belgium, Netherlands, Canada, Hungary, Israel and Argentina. We are conducting our clinical trial for ELVN-002 in the United States, Spain, France, Italy, Australia, Taiwan and South Korea. In the future, we may also conduct clinical trials for ELVN-002 in other countries. We plan to conduct clinical trials for future candidates in the United States and internationally. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from United States clinical trials are intended to serve as the basis for marketing approval in the foreign countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of our applicable jurisdiction. In some cases, the regulatory authority may require clinical trials to include patients in their jurisdiction to support regulatory approval. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fails to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be harmed.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and on-going surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements and regulatory inspection. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

In addition, if the FDA, EMA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current good manufacturing practices ("cGMPs") and good clinical practices ("GCPs") for any clinical trials that we conduct post-approval.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- suspension or restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- fines, restitution, or disgorgement of profits or revenues;
- consent decrees, injunctions or imposition of civil or criminal penalties;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions, or export or import bans;
- voluntary or mandatory product recalls, withdrawals, and/or publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements;
- restrictions or revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions; and
- requirements to conduct additional post-market clinical trials to assess the safety of the product.

The FDA, EMA and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of

government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. Changes to existing policies and regulations can increase our compliance costs or delay our clinical plans.

The FDA, EMA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA, EMA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted in the United States for uses that are not approved by the FDA as reflected in the product's approved labeling, or in other jurisdictions for uses that differ from the labeling or uses approved by the applicable regulatory agencies. While physicians may prescribe products for off-label uses, the FDA, EMA and other regulatory agencies actively enforce laws and regulations that prohibit the promotion of off-label uses by companies, including promotional communications made by companies' sales forces with respect to off-label uses that are not consistent with the approved labeling, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil, criminal and administrative penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue.

The United States federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Where appropriate, we plan to secure approval from the FDA, EMA or comparable foreign regulatory authorities through the use of accelerated registration pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, EMA or comparable regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA, EMA or such other regulatory authorities may seek to withdraw accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our product candidates from the FDA, EMA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. However, because our product candidates are in early development, there can be no assurance that the FDA will permit us to utilize an expedited approval process for any of our product candidates. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Even if our product candidates are granted a designation or qualify for expedited development, it may not actually lead to faster development or expedited regulatory review and approval or increase the likelihood that they will receive FDA approval. For example, if such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval, we will seek feedback from the FDA, EMA or comparable foreign regulatory authorities and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that, after our evaluation of the feedback and other factors, we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of

expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation (e.g., Fast Track designation, Breakthrough Therapy designation or orphan drug designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all, because the FDA's accelerated approval pathways do not guarantee an accelerated review by the FDA. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Where possible, we plan to seek Fast Track designation from the FDA for one or more of our product candidates. Even if one or more of our product candidates receive Fast Track designation, we may be unable to obtain or maintain the benefits associated with the Fast Track designation.

Where possible, we plan to seek Fast Track designation for one or more of our current or future product candidates. Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If any of our product candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

Where possible, we plan to seek Breakthrough Therapy designation from the FDA, which even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

Where possible, we plan to seek Breakthrough Therapy designation for one or more of our current or future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic 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 product candidates 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. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we may seek Breakthrough Therapy designation for one or more of our current or future product candidates, there can be no assurance that it will receive Breakthrough Therapy designation.

Where possible, we plan to pursue an orphan indication for our product candidates to treat CML and potentially others. However, we may not be able to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA, EMA or other comparable foreign regulatory authorities, from approving competing products.

Where possible, we plan to pursue an orphan indication for our product candidates to treat CML and potentially others. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that

the cost of developing the drug will be recovered from sales in the United States. Our target indications may include diseases with large patient populations or may include orphan indications. However, there can be no assurances that we will be able to obtain orphan designations for our product candidates.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product candidate is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug designation for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to priority review. In view of the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the United States pharmaceutical industry. The ACA, which, among other things, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Prior to the Supreme Court's

decision, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and healthcare measures initiated by the Biden administration will impact the ACA, our business, financial condition and results of operations. Complying with any new legislation or change in regulatory requirements could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032. In January 2013, the American Taxpayer Relief Act of 2012, among other things, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan Act of 2021, a sunset provision, effective January 1, 2024, eliminated the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Further, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at increasing competition for prescription drugs. In August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single-source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including pharmaceutical companies, the U.S. Chamber of Commerce, the National Infusion Center Association, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges as well as future legislative, executive, and administrative actions and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear.

At the state level, legislatures have increasingly passed legislation and implemented 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 2021, many states passed or considered state drug price transparency and reporting laws that substantially increase the compliance burdens on pharmaceutical manufacturers. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business, and expose us to greater liability.

We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;

- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, 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 receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. It is also possible that additional governmental action is taken in response to any future public health emergencies.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

The withdrawal of the United Kingdom ("UK") from the EU, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals for our product candidates in the EU, result in restrictions or imposition of taxes and duties for importing our product candidates into the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU.

Inadequate funding for the FDA, the SEC and other United States government agencies or the EMA or comparable foreign regulatory authorities 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, EMA or comparable foreign regulatory authorities 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. In addition, government funding of 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, EMA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the United States government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our relationships with employees, independent contractors, consultants, commercial collaborators, healthcare professionals, clinical investigators, CROs, suppliers, vendors and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to significant losses, including, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, healthcare professionals, clinical investigators, CROs, suppliers, vendors and third-party payors may engage in misconduct or other improper activities. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare

laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as market, sell and distribute our product candidates for which we obtain marketing approval.

The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act ("FCA");

- federal civil and criminal false claims laws, including the FCA, which can be enforced through civil “qui tam” or “whistleblower” actions, and civil monetary penalty laws, including the Civil Monetary Penalties Law, impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent, knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and the regulations that implement both laws (collectively, “HIPAA”), which created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme 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 statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, which imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, created under the ACA and our implementing regulations, which require applicable manufacturers of drugs, devices, biologics and medical supplies for which reimbursement is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS in HHS information related to payments or other transfers of value made to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare providers (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations that apply to our business, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws, state and foreign pharmaceutical compliance, price reporting and transparency laws, which can vary from jurisdiction to jurisdiction, thus complicating compliance efforts, and which can increase our exposure to liabilities and costs of compliance.

We may also be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and data privacy and security laws and regulations will involve on-going substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, exclusion, debarment or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of 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 significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to stringent and changing privacy, data protection and data security laws, regulations and standards as well as policies, contracts and other obligations related to data privacy, data protection and data security. Our actual or perceived failure to comply with such obligations could lead to enforcement or litigation (that could result in fines or penalties), a disruption or cancellation of clinical trials or commercialization of products, reputational harm, or other adverse business effects.

We collect, receive, retain, store, use, share, disclose, transfer, make accessible, disseminate, and otherwise process data (including personal and clinical trial information) relating to our employees and contractors, and other persons. Accordingly, we are, or may become, subject to numerous legal and contractual obligations regarding the privacy, security, protection and appropriate collection, storing, sharing, use, processing, transfer, and disclosure of certain data, including personal information. For example, we are, or may become, subject to various federal, state, local, and foreign laws, directives, and regulations regarding privacy, data protection, and data security, the scope of which are changing, subject to differing interpretations, and may be inconsistent among jurisdictions or conflict with other legal and regulatory requirements. We are also subject to certain contractual obligations to third parties related to privacy, data protection and data security and we strive to comply with our applicable policies and applicable laws, regulations, contractual obligations, and other legal obligations relating to privacy, data protection, and data security, to the extent possible. The regulatory framework for privacy, data protection and data security worldwide is evolving and is likely to remain complex and uncertain for the foreseeable future. Any perception of privacy, data security, or data protection concerns or an inability, by us or third parties that we rely on, to comply with applicable laws, regulations, policies, industry standards, contractual obligations, or other legal obligations, even if unfounded, may result in additional cost and liability to us, harm our reputation, and adversely affect our business, financial condition, and results of operations.

We are not currently classified as a covered entity or business associate under HIPAA. Thus, we are not directly subject to HIPAA's requirements or penalties. The healthcare providers, including certain research institutions from which we may obtain patient or subject health information, may be subject to privacy, security, and breach notification requirements under HIPAA. Additionally, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial penalties if we knowingly receive individually identifiable health information from a HIPAA covered entity, business associate or subcontractor that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we maintain sensitive personally identifiable information, including health and genetic information, that we receive throughout the clinical trial process and in the course of our research collaborations, and may maintain sensitive personally identifiable information received directly from individuals (or their healthcare providers) who may enroll in patient assistance programs if we choose to implement such programs. In addition, we may be subject to state laws requiring security and protection of personal information and notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic information laws may apply directly to our operations and/or those of our collaborators and may impose or be asserted to impose restrictions on our collection, receipt, retention, storage, use, sharing, disclosure, dissemination, transfer or other processing of individuals' personal information, including health information. Individuals from whom we or our collaborators may obtain personal information, including health information, as well as the healthcare providers who may share this information with us, may have statutory or contractual rights that require certain security measures to protect such information or limit the ability to collect, retain, store, use, share, disclose, disseminate, transfer and otherwise process the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy, data protection, and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Additionally, we are subject to additional restrictions and requirements relating to privacy, data protection and data security in other jurisdictions outside the United States in connection with our clinical trials. For example, the collection, use, storage, disclosure, transfer (including cross-border), or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the General Data Protection Regulation ("GDPR"). The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of certain personal data breaches (including to supervisory authorities and potentially affected individuals), and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data outside the European Economic Area ("EEA") to third-party countries that have not been found to provide adequate protection to such personal data, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater, for the most serious of violations. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

While the GDPR applies uniformly across the EU, each EU Member State is permitted to issue nation-specific data protection legislation, which has created inconsistencies on a country-by-country basis. Additionally, we could be subject to recently enacted UK data privacy and protection laws, regulations and standards, if we decide to enroll patients in the UK clinical trials. While the UK General Data Protection Regulation (the "UK GDPR") largely mirrors the GDPR, Brexit and the subsequent implementation of the UK GDPR expose us to two parallel data protection regimes, each of which potentially authorizes similar significant fines and other potentially divergent enforcement actions for certain violations. In addition, on July 16, 2020, the European Court of Justice invalidated the EU-US Privacy Shield Framework, a mechanism under which personal data could be transferred from the EEA to entities in the United States that had self-certified under the Privacy Shield Framework. The Court also called into question the Standard Contractual Clauses ("SCCs"), noting adequate safeguards must be met for SCCs to be valid. Use of the SCCs must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular, applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place. Additionally, the European Commission has adopted new SCCs that are required to be implemented. The UK also has issued new standard contractual clauses, similar to the SCCs, that also are required to be implemented. On March 25, 2022, the United States and EU announced an "agreement in principle" to replace the EU-U.S. Privacy Shield transfer framework with the Trans-Atlantic Data Privacy Framework ("TADTF"). On July 10, 2023, the European Commission adopted an adequacy decision in relation to the TADTF, since renamed the EU-U.S. Data Privacy Framework ("EU-U.S. DPF"), allowing the EU-U.S. DPF to be utilized as a means of legitimizing EU-U.S. personal data transfers for participating entities. The UK and U.S. also established a UK Extension to the EU-U.S. DPF, effective as of October 12, 2023 (the "UK Extension"), whereby participants in the EU-U.S. DPF who participate in the UK Extension may rely upon the UK Extension as a means to legitimize personal data transfers from the UK to the U.S. The EU-U.S. DPF has faced a legal challenge, and it and the UK Extension may be subject to additional legal challenges, from privacy advocacy groups or others, and the European Commission's adequacy decision regarding the EU-U.S. DPF provides that the EU-U.S. DPF will be subject to future reviews and may be subject to suspension, amendment, repeal, or limitations to its scope by the European Commission. We have encountered, and may continue to encounter, difficulties putting in place SCCs with certain personal data exporters. As supervisory authorities issue further guidance on personal data export mechanisms, including on the new SCCs, and/or start taking enforcement action, our compliance costs could increase. More generally, we may be subject to complaints and/or regulatory investigations or fines relating to cross-border personal data transfers, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we may conduct clinical trials, this could negatively impact our business. Furthermore, On June 28, 2021, the European Commission issued an adequacy decision under the GDPR and the Law Enforcement Directive, pursuant to which personal data generally may be transferred from the EU to the UK without restriction; however, this adequacy decision is subject to a four-year "sunset" period, after which the European Commission's adequacy decision

may be renewed. During that period, the European Commission will monitor the legal situation in the UK and may intervene at any time with respect to its adequacy decision. The UK's adequacy determination therefore is subject to future uncertainty and may be subject to modification or revocation in the future, with the UK potentially being considered an inadequate third country under the GDPR, in which case transfers of personal data from the EEA to the UK will require a transfer mechanism, such as SCCs. Furthermore, there will be increasing scope for divergence in application, interpretation, and enforcement of the data protection law as between the UK and the EEA. This may increase the complexity of transferring personal data across borders.

Similar laws have been proposed in other foreign jurisdictions. For example, on August 20, 2021, the Personal Information Protection Law ("PIPL") of the People's Republic of China ("PRC") was adopted and went into effect on November 1, 2021. The PIPL shares similarities with the GDPR, including extraterritorial application, data minimization, data localization, and purpose limitation requirements, and obligations to provide certain notices and rights to citizens of the PRC. The PIPL allows for fines of up to 50 million renminbi or 5% of a covered company's revenue in the prior year. If additional laws are passed, such laws may have potentially conflicting requirements that would make compliance challenging. Such laws may require us to modify our operations, and may limit our ability to collect, retain, store, use, share, disclose, transfer, disseminate, and otherwise process personal data, may require additional investment of resources in compliance programs, impact strategies and could result in increased compliance costs and/or changes in our ongoing or planned business practices and policies.

We may also be subject to federal and state privacy, data protection and data security laws and regulations in the United States including, without limitation, laws that regulate personal information, including health information. For example, California has enacted the California Consumer Privacy Act ("CCPA"), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy, data protection, and data security obligations on entities handling personal information of California consumers, devices, or households. The CCPA requires covered companies to provide new disclosures to California consumers about such companies' data collection, use and sharing practices and provide such consumers new ways to opt-out of certain sales of personal information. The CCPA also provides consumers with a private right of action in certain data breach situations. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions for violations on July 1, 2020. Moreover, the California Privacy Rights Act ("CPRA"), which significantly modified the CCPA, including by imposing additional obligations on covered companies and expanding consumers' rights with respect to certain sensitive personal information, became operative on January 1, 2023, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA.

The CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the United States. The CCPA has prompted a number of proposals for federal and state privacy legislation, some of which have been enacted. Many of these proposed and enacted laws are comprehensive privacy statutes that impose obligations similar to the CCPA. For example, Colorado enacted the Colorado Privacy Act ("CPA"), legislation similar to the CCPA that has taken effect in 2023; Connecticut, Utah, and Virginia have also enacted legislation similar to the CCPA and CPA that took effect in 2023; Florida, Montana, Oregon, and Texas have enacted similar legislation that are effective in July 2024; Delaware, Iowa, New Jersey, and Tennessee have enacted similar legislation that will take effect in 2025; and Indiana has enacted similar legislation that will take effect in 2026. With regard to the CPA, we are monitoring developments closely in view of our operations in Colorado. The CPA and its implementing rules, the final versions of which were issued by the Colorado Attorney General, became effective July 1, 2023. Further, other states have enacted laws that cover certain aspects of the collection, use, disclosure, and/or other processing of health information, such as Washington's My Health, My Data Act, which, among other things, provides for a private right of action. The U.S. federal government also is contemplating federal privacy legislation. We may be required to modify our policies and practices and otherwise to incur additional costs and expenses in an effort to comply with the CPA and other new and evolving privacy legislation. Collectively, these reflect a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging.

We may also publish privacy policies and other documentation regarding our collection, processing, use and disclosure of personal information. Although we endeavor to comply with our published policies and documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or contractors fail to comply with our published policies and documentation. Such failures can subject us to potential foreign, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices.

The number and scope of obligations related to privacy, data protection and data security are changing, subject to differing applications and interpretations, and may be inconsistent between jurisdictions or in conflict with each other. As a result, compliance with United States and foreign privacy, data protection, and data security laws and regulations could require us to take

on more onerous obligations in our contracts, restrict our ability to collect, retain, store, use, share, disclose, transfer, disseminate, and otherwise process data, or in some cases, impact our ability to operate in certain jurisdictions. Although we endeavor to comply with our published policies, other documentation, and all applicable privacy and security laws and regulations, we may at times fail to do so or may be perceived to have failed to do so. Any actual or alleged failure to comply with such obligations could result in governmental investigations, proceedings and enforcement actions (which could include civil or criminal fines or penalties), private litigation or adverse publicity, harm to our reputation, and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information or impose other obligations or restrictions in connection with our use, retention and other processing of information, and we may otherwise face contractual restrictions applicable to our use, retention, and other processing of information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery and anti-corruption laws and anti-money laundering laws, including laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

We are subject to the FCPA, the U.S. domestic public corruption and commercial bribery statutes contained in 18 U.S.C. § 201, the U.S. Travel Act and possibly other anti-bribery and anti-corruption laws and anti-money laundering laws in countries outside of the United States in which we conduct our activities. Anti-corruption and anti-bribery laws have been enforced aggressively in recent years and are interpreted broadly to generally prohibit companies, their employees, agents, representatives, business partners, and third-party intermediaries from authorizing, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector.

We may leverage third parties to sell our products and conduct our business abroad. We, our employees, agents, representatives, business partners and third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities and may be held liable for the corrupt or other illegal activities of these employees, agents, representatives, business partners or third-party intermediaries even if we do not explicitly authorize such activities. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore may involve significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently, the SEC and DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. We cannot assure you that all of our employees, agents, representatives, business partners or third-party intermediaries will not take actions in violation of applicable law for which we may be ultimately held responsible. As we commercialize our product candidates and increase our international sales and business, our risks under these laws may increase. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

These laws also require that we keep accurate books and records and maintain internal controls and compliance procedures designed to prevent any such actions. While we have policies and procedures to address compliance with such laws, we cannot assure you that none of our employees, agents, representatives, business partners or third-party intermediaries will take actions in violation of our policies and applicable law, for which we may be ultimately held responsible.

Any allegations or violation of the FCPA or other applicable anti-bribery and anti-corruption laws and anti-money laundering laws could result in whistleblower complaints, sanctions, settlements, prosecution, enforcement actions, fines, damages, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions, or suspension or debarment from government

contracts, all of which may have an adverse effect on our reputation, business, results of operations, and prospects. Responding to any investigation or action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, United States export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by United States sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are 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 sublease for our corporate headquarters expires on December 30, 2024. We are assessing alternative spaces and, if we move our facility, such relocation, including our obligation to decontaminate our facility, may delay our product development, expose us to additional liabilities, and increase our costs.

Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive 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 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.

Any legal proceedings or claims against us could be costly and time-consuming to defend and could harm our reputation regardless of the outcome.

We may in the future become subject to legal proceedings and claims that arise in the ordinary course of business, including intellectual property, product liability, employment or employee misclassification, class action, whistleblower and other litigation claims, and governmental and other regulatory investigations and proceedings. We may incur liability under our agreements with third parties, and we are not always indemnified under such agreements. We may also be exposed to increased litigation from stockholders, suppliers and other third parties due to the combination of our business and Former Enliven's business. For example, we were involved in a legal proceeding in connection with the Merger, which required the payment of a mootness fee and was voluntarily dismissed by the plaintiff in January 2023.

Such matters can be time-consuming, divert management's attention and resources, cause us to incur significant expenses or liability, or require us to change our business practices. In addition, the expense of litigation and the timing of this expense from period to period are difficult to estimate, subject to change, and could adversely affect our financial condition and results of operations. Because of the potential risks, expenses, and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Any of the foregoing could adversely affect our business, financial condition, and results of operations.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

Our success is highly dependent on our ability to attract, hire and retain highly skilled executive officers and employees.

We currently have a small team focused on research and development of small molecule kinase inhibitors. Our ability to discover and develop any product candidates is dependent on our chemists. To succeed, we must recruit, hire, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff, particularly Sam Kintz, our President, Chief Executive Officer and director and Joseph P. Lyssikatos, our Chief Scientific Officer and director. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We do not maintain “Key Person” insurance for any of our executives or other employees. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

Our scientific and clinical advisors and consultants may enter into non-compete agreements with us and, given a shifting legal landscape, such agreements may or may not continue to be enforceable. Our scientific and clinical advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting or employment relationships with our scientific founders and other scientific and clinical advisors and consultants, or if they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be significantly harmed.

Our reliance on a limited number of employees who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business.

As of March 31, 2024, we had 50 full-time employees. Of these employees, 38 are engaged in research or product development and clinical activities. The small size of our centralized team may limit our ability to devote adequate personnel, time, and resources to support our operations or research and development activities, and the management of financial, accounting, and reporting matters. If our team fails to provide adequate administrative, research and development, or other services across our organization, our business, financial condition, and results of operations could be harmed.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of March 31, 2024, we had 50 full-time employees. Of these employees, 38 are engaged in research or product development and clinical activities. In order to successfully implement our development and commercialization plans and strategies, we expect to need significant additional managerial, operational, sales, marketing, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, retaining and motivating our current and additional employees;
- managing our internal development efforts effectively, including the preclinical, clinical, FDA, EMA and other comparable foreign regulatory agencies’ review process for ELVN-001, ELVN-002, and any other product candidates while complying with any contractual obligations to contractors and other third parties;
- managing increasing operational and managerial complexity;
- complying with additional regulatory and compliance requirements related to advancing our product candidates and research programs; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize ELVN-001, ELVN-002 and other research programs will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of research, clinical development, regulatory functions and manufacturing. We also rely, and for the foreseeable future will continue to rely, on one or more employers of record to engage workers outside of the United States, which could expose the Company to liability for its employment practices outside of the United States and for liabilities associated with the employment practices of any such employer of record. There can be no assurance that the services of independent organizations, employers of record, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval for any of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize ELVN-001, ELVN-002 and any other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer actual or suspected security or data privacy incidents or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal information, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations, and potentially significant delays in our clinical trials and delivery of product to market.

In the ordinary course of our business, we collect, store, process, and transmit large amounts of data, including intellectual property, proprietary or confidential data, employee data, and personal information. We also collect, store, process, and transmit health information, in connection with our clinical trials. It is critical that we do so in a secure manner to maintain the confidentiality, integrity, and availability of such data. Our obligations under applicable laws, regulations, contracts, industry standards, and other documentation may include maintaining the confidentiality, integrity, and availability of such data in our possession or control, maintaining reasonable and appropriate security safeguards as part of an information security program, and restrictions on the use and disclosure of such data. These obligations create potential legal liability to regulators, business partners, clinical trial participants, employees, and other relevant stakeholders.

We have outsourced certain elements of our operations (including elements of our information technology infrastructure) to third parties and have incorporated third-party technology into our information technology infrastructure, which collects, processes, transmits and stores intellectual property, proprietary or confidential data, employee data, and personal information. As a result, we manage a number of third-party providers who may or could have access to our information technology systems or to our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to additional third parties.

Despite the implementation of security measures designed to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and external processing and storage systems (e.g., cloud), and those of our third-party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are from time to time vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, power outages, natural disasters, global pandemics (such as COVID-19), terrorism, acts of vandalism, war and telecommunication and electrical failures, as well as security breaches and incidents from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties (including nation- state and nation-state supported actors), or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, viruses, denial-of-service attacks, phishing attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to the unauthorized access to or acquisition, use, corruption, loss, destruction, alteration or dissemination of, or damage to, our data.

For example, from time to time, we experience an increase in phishing and social engineering attacks from third parties in connection with the increase in remote work in recent years. As a result, we, as well as any of our CROs, clinical trial sites, manufacturers, other contractors or consultants who may be operating in remote work environments may have increased cyber security and data security risks, due to increased use of home wi-fi networks and virtual private networks, as well as increased disbursement of physical machines. While we implement information technology controls designed to reduce the risk of a cyber security or data security incident, there is no guarantee that these measures will be adequate to safeguard all systems, especially with an increased number of employees primarily working remotely. Additionally, we are migrating certain data analysis functions from outsourced providers to in-house resources, which may create additional security risks.

To the extent that any disruption or security incident were to result in any unauthorized, unlawful, or accidental access to, or acquisition, use, corruption, loss, destruction, unavailability, alteration or dissemination of, or damage to, our data (including confidential or personal information) or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. There can be no assurance that our data protection and security efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties, will prevent significant breakdowns or breaches in systems or other cyber security incidents that cause unauthorized, unlawful, or accidental access to or acquisition, use, corruption, loss, destruction, unavailability, alteration or dissemination of, or damage to, our data that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs (including clinical trials) and the development of our product candidates could be delayed. In addition, significant disruptions of our internal information technology systems or security incidents could result in the loss, misappropriation, and/or unauthorized access, use, acquisition, or disclosure of, or the prevention of access to, data (including trade secrets or other confidential data, intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized, unlawful, or accidental access, use, or disclosure of personal information, including personal information regarding our employees or business partners, could harm our reputation directly, compel us to comply with breach notification laws, subject us to financial exposure related to investigation of the incident (including cost of forensic examinations), subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal data, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

We may also be required to notify governmental authorities and/or affected individuals of breaches involving personal information. For example, all 50 states have laws including obligations to provide notification of security breaches of computer databases that contain personal information to affected individuals, state regulators, and/or others. These laws are not consistent, and compliance in the event of a widespread security breach or incident may be difficult and costly. We also may be contractually required to notify affected individuals or other relevant stakeholders of a security breach or incident. Regardless of our security measures and contractual protections, any actual or perceived security breach or incident or breach of our contractual obligations could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach or incident. Notifications and follow-up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We expect to incur significant costs in an effort to detect and prevent security breaches and incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach or incident.

We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. We and our third-party providers may not have the resources or technical sophistication to anticipate or prevent all such cyber-attacks. Techniques used to obtain unauthorized access to systems are increasingly sophisticated, change frequently and may not be known until launched against us or our third-party providers. While we have no reason to believe that we have experienced a data security incident that we have not discovered, attackers have become very sophisticated in the way they conceal their unauthorized access to systems, and many companies that have been attacked are not aware that they have been attacked. Any incident that leads to loss of or unauthorized access to, or use, alteration, or disclosure of information of individuals, including but not limited to personal information regarding our employees, could disrupt our business, harm our reputation, compel us to comply with applicable data breach notification laws, subject us to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that

protect the privacy and security of personal information. This could result in increased costs to us and result in significant legal and financial exposure and/or reputational harm.

There have been and may continue to be significant supply chain attacks (such as the attacks resulting from vulnerabilities in SolarWinds Orion, Accellion FTA, Microsoft Exchange, Codecov, Kaseya VSA, MOVEit, Okta, and other widely-used software and technology infrastructure) and we cannot guarantee that our or our third-party providers' systems have not been breached or that they do not contain exploitable defects or bugs that could result in a security breach or incident of, or other disruption to, our systems and networks or the systems and networks of third parties that support us. Our ability to monitor our third-party providers' security measures is limited, and, in any event, malicious third parties may be able to circumvent those security measures, resulting in the unauthorized, unlawful, or accidental access to, misuse, disclosure, loss or destruction of our data, including employee personal information and other sensitive information. We have not experienced a cybersecurity incident that has been determined to be material, but our and our third-party providers' and partners' information technology systems have and may in the future experience cybersecurity incidents or vulnerabilities that could be exploited from inadvertent or intentional actions of our employees, third-party providers, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise, including organized criminal groups, "hacktivists," nation states and others. Additionally, due to the geopolitical unrest associated with Russia's invasion of Ukraine and the conflict in the Middle East, we and our CROs, contractors, and other third-party providers and collaborators may be vulnerable to heightened risks of cybersecurity incidents and security and privacy breaches.

Security incidents that impact our information technology systems could result in breaches of our contracts (some of which may not have liability limitations and/or require us to indemnify affected parties) and could lead to litigation with collaborators, clinical trial participants, or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, adversely affect our reputation or otherwise adversely affect our business. Similarly, security incidents could lead to regulatory investigations. We could be required to fundamentally change our business activities and practices in response to such litigation, which could have an adverse effect on our business.

We may not have applicable or otherwise adequate insurance to protect us from, or adequately mitigate, liabilities or damages resulting from cyber or privacy incidents. The successful assertion of one or more large claims against us that exceeds any available insurance coverage that we might have, or results in changes to insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that insurance coverage will be available on acceptable terms or that insurers will not deny coverage as to any future claim.

Further, any disruption or security incident that does or is perceived to result in unauthorized, unlawful, or accidental access to or acquisition, use, corruption, loss, destruction or alteration of, or damage to, our data, including our confidential or proprietary data, could expose us to litigation and governmental investigations, could delay the further development and commercialization of our product candidates, and could subject us to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We currently do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on our own. If we are unable to enter into such arrangements when needed, on

acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We may seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries, such as the lack of pathways for accelerated drug approval, may result in foreign regulatory approvals taking longer and being more costly than obtaining approval in the United States;
- foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or our interpretation of data from nonclinical studies or clinical trials;
- approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with legal requirements applicable to privacy, data protection, information security and other matters;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes and government payors in foreign countries;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, trade policies, treaties and tariffs.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no

assurance that our patent applications or the patent applications of our future licensors will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our and our licensors' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We cannot be certain that the claims in our United States pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, or those of our future licensors, will be considered patentable by the United States Patent and Trademark Office ("USPTO"), courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our future issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- the FDA and its counterparts in other countries require detailed information of clinical trials to be included in certain public forums which may limit the patentability of certain disclosed inventions;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;
- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we and any future licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or any future licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

We may be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising from, for example, conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. In addition, the laws of some countries may prohibit the contractual assignment of intellectual property prior to its creation. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. We cannot be certain that we are

the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority or entitlement disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Since patent applications in the United States and other countries are confidential for a period of time after filing, at any moment in time, we cannot be certain that we were in the past or will be in the future the first to file any patent application related to our product candidates. For example, some patent applications in the United States may be maintained in secrecy until the patents are issued. Further, publications in the scientific literature often lag behind actual discoveries. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in the public domain. In some cases, the work of certain academic researchers in the cancer therapeutics field has entered the public domain, which may preclude our ability to obtain patent protection for certain inventions relating to such work. Consequently, we cannot be certain that others have not filed patent applications for technology covered by our owned, and any of our future in-licensed, issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent or first to file an application for the technology. In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees. In addition, the laws of some foreign countries, such as China where some of our CROs are based, may not protect our intellectual property rights to the same extent as do the laws of the United States and, even if they do, uneven enforcement and procedural barriers may exist in such countries. Damage awards resulting from successful litigation in foreign jurisdictions may not be in amounts commensurate with damage awards in the U.S.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition to the protection provided by our patent estate, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not amenable to patent protection. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, or that our trade secrets and other confidential proprietary information will not be disclosed. In addition, while we have undertaken reasonable efforts to ensure such agreements are enforceable and that employees and third parties comply with their obligations thereunder, these agreements may be found insufficient by a court of law or may be breached, or we may not enter into sufficient agreements with such individuals in the first instance, in either case potentially resulting in the unauthorized use or disclosure of our trade secrets and other intellectual property, including to our competitors, which could cause us to lose any competitive advantage resulting from this intellectual property. Individuals not subject to invention assignment agreements may make adverse ownership claims to our current and future intellectual property. Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products, if approved, and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, 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, our competitive position would be harmed. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable, and we may not be able to obtain adequate remedies for such breaches.

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

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our future licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates. In fact, patent applications may not issue as patents at all.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and our scope can be reinterpreted after issuance. Even if patent applications we own or in-license in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of our future licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to our inventorship, scope, validity or enforceability, and our patents or the patents of our future licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review ("PGR") and *inter partes* review ("IPR"), or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, our patents or the patents of our future licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our future licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, 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 product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our future licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or our future licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- 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 may not develop additional proprietary technologies that are patentable;
- we or our licensors may fail to meet obligations to the U.S. government with respect to any future in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- we may not successfully commercialize the product candidates, if approved, before our relevant patents expire;
- the patents of others or pending or future applications of others may have an adverse effect on 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, it could significantly harm our business, results of operations and prospects.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party United States and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. 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, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Generative artificial intelligence resources that are publicly available present a risk that a company may inadvertently obtain, incorporate, or use a third party's intellectual property. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or

- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this quarterly report on Form 10-Q, others may hold proprietary rights that could prevent our product candidates from being marketed. It is possible that a third party may assert a claim of patent infringement directed at any of our product candidates. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates, treatment indications, or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and results of operations. In addition, intellectual property litigation, regardless of our outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for development and commercialization of our product candidates, either as a monotherapy or in combination with other drugs. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be involved in lawsuits to protect or enforce our patents or our future licensors' patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents or our future licensors' patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent or the patent of our future licensors is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of sufficient written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and/or unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our future licensors, and the patent examiners are unaware during prosecution. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our future licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

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.

In Europe, beginning June 1, 2023, European applications and patents may be subjected to the jurisdiction of the Unified Patent Court (“UPC”). Also, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty. As a single court system can invalidate a European patent, we, where applicable may opt out of the UPC and as such, each European patent would need to be challenged in each individual country.

Changes in United States patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. For example, the Supreme Court of the United States held in Amgen v. Sanofi (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. In addition, the Federal circuit recently issued a decision involving the interaction of patent term adjustment, terminal disclaimers and obvious-type double patenting. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the United States Congress, the United States federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future.

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. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. 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 patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our United States patents or those of our future licensors may be eligible for limited patent term restoration under the Hatch-Waxman Act, or patent term extension in certain foreign countries. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout the world.

Although we have pending patent applications in the United States and will have pending patent applications in other countries in the future, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents, the patents of our future licensors, 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 many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or our future licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent 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 or the patents of our future licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our future licensors 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 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 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.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications and those of our future licensors. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, 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. If such an event were to occur, it could have a material adverse effect on our business.

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.

We intend to use trademarks or trade names to brand our products and our clinical trials. Our trademarks or trade names may be challenged, infringed, 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. We have not registered any of our trademarks, which could adversely affect our ability to defend our trademark rights. 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 trademarks that incorporate variations of our 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 affect our financial condition or results of operations.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, and other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

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

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These 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 technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, 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 future licensors fail to prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our future product candidates that are the subject of such licensed rights could be adversely affected.

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

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. 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. In that event, 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 product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;

- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we 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 license in the future prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

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

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for United States-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-United States manufacturers.

Although we do not currently own issued patents or pending patent applications that have been generated through the use of United States government funding, we may acquire or license in the future intellectual property rights that have been generated through the use of United States government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the United States government has certain rights in inventions developed with government funding. On December 8, 2023, the National Institute of Standards and Technology ("NIST") released the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* ("Guidance") to the public for comment. The Guidance represents the first federal framework specifying that price can be a factor in considering whether the government may exercise its march-in authority pursuant to 35 U.S.C. 200 et seq. (Bayh-Dole). These United States government march-in rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations, also referred to as march-in rights. If the United States government exercised its march-in rights in our future intellectual property rights that are generated through the use of United States government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the United States government for the exercise of such rights. The United States government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the United States government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for United States industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States industry may limit our ability to contract with non-United States product manufacturers for products covered by such intellectual property.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct preclinical studies and clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.

We currently utilize and depend upon, and plan to utilize and depend upon, independent investigators and collaborators, such as medical institutions, CROs, CMOs, and strategic partners to conduct and support our preclinical studies and clinical trials under agreements with us. For example, we use Pharmaron to conduct preclinical studies and clinical trials and provide us with APIs. Since Pharmaron is located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. For example, a trade war could lead to tariffs on the APIs we obtain from Pharmaron. Any of these matters could materially and adversely affect our business and results of operations. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs.

In the future, we may also rely on third parties for the manufacture of any companion diagnostics we may develop. These third parties have had and will continue to have a significant role in the conduct of our preclinical studies and clinical trials and the subsequent collection and analysis of data.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

Our third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the amount or timing of resources that any such third party will devote to our preclinical studies or clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. Some of these third parties may terminate their engagements with us at any time. We also expect to have to negotiate budgets and contracts with CROs, clinical trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. If we need to enter into alternative arrangements with, or replace or add any third parties, it would involve substantial cost and require extensive management time and focus, or involve a transition period, and may delay our drug development activities, as well as materially impact our ability to meet our desired clinical development timelines.

Our heavy reliance on these third parties for such drug development activities will reduce our control over these activities. As a result, we will have less direct control over the conduct, timing and completion of preclinical studies and clinical trials and 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. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMP regulations and

will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients, may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, or if these third parties need to be replaced, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials and expect to do so ultimately for commercialization, and the loss of these third parties or their inability to supply us with sufficient quality and quantities of our product candidates or such quantities at an acceptable cost could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. Any supply interruption in limited or sole sourced materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. To date, we have obtained APIs and drug product for our product candidates from certain single-source CMOs. Any performance failures by such CMOs could materially harm our business. We do not have long-term supply agreements and may not be able to secure supply agreements, and we purchase our required drug product on a purchase order basis, which means that aside from any binding purchase orders we have from time to time, our supplier could cease supplying to us or change the terms on which it is willing to continue supplying to us at any time. We have experienced from time to time, and in the future may experience, an unexpected loss of supply of any of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise. As a result, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing preclinical studies or clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required 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:

- the failure of the third party to manufacture our product candidates according to our schedule and specifications, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements, including cGMPs;
- the breach by the third-party contractors of our agreements with them;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the inability of our third-party contractors to import or export our product candidates internationally;
- clinical supplies not being delivered to clinical sites on time, or at all, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, or at all, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know- how.

We do not have complete control over all aspects of the manufacturing process of our contract manufacturing partners and are dependent on these contract manufacturing partners for compliance with cGMP regulations for manufacturing both APIs and finished drug products. Our CMOs are also subject to import and export rules and restrictions, which may impact their ability to acquire materials used in the manufacturing of our product candidates or export our manufactured investigational products to the countries where our clinical trials are conducted. To date, we have obtained most of our APIs and drug product for our product candidates, from single-source third-party CMOs. We are in the process of developing our supply chain for each of our product candidates and intend to put in place framework agreements under which third-party CMOs will generally provide us with necessary quantities of APIs and drug product on a project-by-project basis based on our development needs. As we advance our product candidates through development, we are considering our lack of redundant supply for the APIs and drug product for each of our product candidates to protect against any potential supply disruptions. However, we may be unsuccessful in putting in place such framework agreements or protecting against potential supply disruptions.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable regulatory authorities, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we will need to find alternative manufacturing facilities, and those new facilities would need to be inspected and approved by FDA, EMA or comparable regulatory authority prior to commencing manufacturing, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

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

Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce our products, if approved, either at a third party's facility or in any of our facilities, we will need to comply with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages of qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our precision medicines as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our precision medicines for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

If our third-party manufacturers use hazardous materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous

materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, product candidates, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products, product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursues partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

If we decide to establish collaborations but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. We may also seek strategic collaborations to develop combination therapy strategies for our portfolio products, and/or maximize portfolio value globally through selective co-development and/or commercialization collaborations. Any of these relationships 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.

We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration depends, 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 preclinical studies or clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign 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 drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative

arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative efforts and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of business combinations among large pharmaceutical companies, and business combinations could result in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, we may not be able to negotiate 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 a product candidate, reduce or delay our development program or one or more of our other research programs, delay our 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 increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may enter into collaborations with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

If we enter into any collaboration arrangements with any third parties for the development and commercialization of our product candidates, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business combination or sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- we may grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for 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;

- collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our product candidates;
- collaborators may own or co-own intellectual property covering our products or product candidates that result from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our programs, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;
- the timing and outcomes of preclinical studies and clinical trials for ELVN-001, ELVN-002 and any product candidates from our research programs, or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- our ability to develop combination drug products or companion diagnostics;
- our ability to acquire drug product for combination trials;
- competition from existing and potential future products that compete with ELVN-001, ELVN-002 or any of our research programs, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of ELVN-001, ELVN-002 or any of our other research programs;
- the level of demand for any of our product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with ELVN-001, ELVN-002 or any of our other research programs;
- our ability to commercialize ELVN-001, ELVN-002 or any of our research programs, if approved, inside and outside of the United States, either independently or working with third parties;

- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic and political environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

Risks Related to Our Common Stock

The market price of our common stock may be volatile and may drop.

The market price of our common stock has been and is likely to continue to be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- timing and results of INDs, preclinical studies and clinical trials of our product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- geo-political developments, general market or macroeconomic conditions including inflation and interest rates;
- market conditions in the pharmaceutical and biotechnology sectors;
- expiration of market stand-off or lock-up agreements;
- changes in the structure of healthcare payment systems;
- announcement of expectation of additional financing efforts;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations and continued development of our product candidates;
- trading volume of our common stock;

- publicity or announcements by competitors of new commercial products or success of competitive products (such as asciminib), clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- the impact of any natural disasters, public health emergencies, health epidemics or other outbreaks, such as the COVID-19 pandemic;
- the introduction of technological innovations or new product candidates that compete with our products and services; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, macroeconomic conditions, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19, the Russia-Ukraine and Israel-Hamas conflicts, or otherwise could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

We will need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital on favorable terms, on a timely basis or at all, we would be forced to delay, reduce or eliminate our product development and clinical programs and may not have the capital required to otherwise operate our business.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We have not generated any revenues from the commercial sale of products and will not be able to generate any product revenues until, and only if, we receive approval to sell our product candidates from the FDA or other regulatory authorities. As of March 31, 2024, we had $320.5 million in cash, cash equivalents and marketable securities. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations into late 2026. However, as we have not generated any revenue from commercial sales to date and do not expect to generate any revenue for several years, if ever, we will need to raise substantial additional capital in order to fund our general corporate activities and to fund our research and development, including our currently planned clinical trials and plans for new clinical trials and product development.

We may seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations or, if such funds are available, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution and new investors could gain rights, preferences and privileges senior to the holders of common stock. On June 23, 2023, we filed a shelf registration statement on Form S-3 with the SEC, which was declared effective by the SEC on July 3, 2023, which allows us to undertake various equity and debt offerings up to $400.0 million (the "Shelf Registration"). On June 23, 2023, we also entered into an Open Market Sale Agreement℠ (the "Sales Agreement") with Jefferies LLC (the "Sales Agent"), pursuant to which we may offer and sell shares of our common stock, from time to time through an "at-the-market" program under the Securities Act, having an aggregate offering price of up to $200.0 million through the Sales Agent. Additionally, in March 2024, we sold common stock and Pre-Funded Warrants in the Private Placement and received aggregate gross proceeds of $90.0 million. We do not have any committed external source of funds. Debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that may not be favorable.

Given our capital constraints, we will need to prioritize spending on our clinical and preclinical programs. If we are unable to raise sufficient funds to support our current and planned operations, we may elect to discontinue certain of our ongoing activities or programs. Our inability to raise additional funds could also prevent us from taking advantage of opportunities to pursue promising new or existing programs in the future. In the event that we would need to obtain additional funding, our ability to raise or access capital may be affected by macroeconomic events and disruptions to the banking and financial sectors. Failures of banks and other financial institutions, such as Silicon Valley Bank in March 2023, or issues in the broader U.S. financial system, including the federal government's potential failure to raise the debt ceiling, may impact the broader capital markets, and in turn, may impact our ability

to access those markets or negatively impact our investments. Further, a tightening of credit markets and lending standards could make it more difficult for us to raise capital through either debt or equity offerings on commercially reasonable terms or at all.

Our forecasts regarding our beliefs in the sufficiency of our financial resources to support our current and planned operations are forward-looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. These estimates are based on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than currently expected.

Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and marketable securities and to timely pay key vendors and others.

Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and marketable securities and to timely pay key vendors and others. If banks and financial institutions with whom we have banking relationships enter receivership or become insolvent in the future, we may be unable to access, and we may lose, some or all of our existing cash, cash equivalents and marketable securities to the extent those funds are not insured or otherwise protected by the FDIC. In addition, in such circumstances we might not be able to timely pay key vendors and others. We regularly maintain cash balances that are not insured or are in excess of the FDIC's insurance limit. Any delay in our ability to access our cash, cash equivalents and marketable securities (or the loss of some or all of such funds) or to timely pay key vendors and others could have a material adverse effect on our operations and cause us to need to seek additional capital sooner than planned.

We have incurred and will continue to incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

We have incurred and will continue to incur significant legal, accounting and other expenses as a public company that Former Enliven did not incur as a private company, including costs associated with public company reporting obligations under the Exchange Act. Our executive officers and other personnel have devoted and will continue to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Once we are no longer an emerging growth company, a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.

We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. However, as an emerging growth company, we may take advantage of exemptions from various requirements such as an exemption from the requirement to have our independent auditors attest to our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 as well as an exemption from the "say on pay" voting requirements pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. After we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which may allow us to take advantage of some of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Even after we no longer qualify as an emerging growth company, we expect to still qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, in at least the near term, which will allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in the definitive proxy statement/prospectus and in our periodic reports and proxy statements. Once we are no longer an emerging growth company, a smaller reporting company or otherwise qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses we could face additional

costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Our issuance of additional capital stock pursuant to our equity incentive plan and employee stock purchase plan, or in connection with financings, acquisitions, or otherwise will dilute the interests of other security holders and may depress the price of our common stock.

We expect to grant equity awards to employees, directors and consultants under our equity incentive plan and employee stock purchase plan. We will need substantial additional funding before we can complete the development of our product candidates. We may also raise capital through equity financings in the future. For example, in March 2024, we sold 5,357,144 shares of our common stock and Pre-Funded Warrants to purchase 1,071,505 shares of our common stock in the Private Placement. As part of our growth strategy, we may seek to acquire companies and issue equity securities to pay for any such acquisition. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

Provisions that are in our certificate of incorporation and bylaws and provisions 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 management.

Provisions that are included in our certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our common stockholders might otherwise receive a premium price 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 will be 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:

- continue the use of a classified board of directors such that not all members of our board of directors are elected at one time;
- 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;
- provide for advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and for nominations to our board of directors;
- limit who may call stockholder meetings;
- prohibit actions by our stockholders by written consent;
- require that stockholder actions be effected at a duly called stockholders meeting;
- 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 percent of the votes that all of our stockholders would be entitled to cast to amend or repeal certain provisions of our certificate of incorporation or for our stockholders to amend our bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the “DGCL”), which generally prohibits a person who, together with their affiliates and associates, owns 15% or more of the company’s outstanding voting stock from, among other things, merging or combining with the company for a period of three years after the date of the transaction in which the person acquired ownership of 15% or more of the company’s outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation generally provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation provides that, unless the company consents 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) is the sole and exclusive forum for the following types of proceedings: (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to the company or our stockholders, (3) 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 (4) 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. This choice of forum provision will not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which federal courts have exclusive jurisdiction.

This exclusive forum provision may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees or stockholders, which may discourage such lawsuits against us and our directors, officers and other employees and stockholders. Alternatively, if a court were to find the choice of forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

Our ability to utilize our NOLs and tax credit carryforwards may be subject to limitations.

Following the Merger, our NOLs are attributable to current year losses, as well as both the historic pre-Merger NOLs of Former Enliven and our historic pre-Merger NOLs, subject to applicable limitations.

As of December 31, 2023, the Company had federal NOLs of approximately $185.3 million, of which approximately $177.3 million do not expire and approximately $8.0 million will begin to expire in 2037 for U.S. federal tax purposes. As of December 31, 2023, the Company also had California, Colorado and Massachusetts NOLs of approximately $126.7 million, $4,000 and $124.2 million, respectively, which will expire at various dates through 2043 for state tax purposes.

As of December 31, 2023, the Company had federal tax credit carryforwards of approximately $10.5 million, which will begin to expire in 2036 for U.S. federal tax purposes. The Company also had state tax credit carryforwards of approximately $1.3 million, of which approximately $0.5 million will not expire. The remaining state tax credit carryforwards will expire at various dates through 2038.

In general, our ability to use our NOLs and tax credit carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs and tax credit carryforwards. For U.S. federal income tax purposes, under the Tax Cuts and Jobs Act of 2017 ("TCJA"), as amended by the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but for taxable years beginning after December 31, 2020, the deductibility of federal NOLs is limited to 80% of current year taxable income. It is uncertain whether and to what extent various states will conform to the federal tax laws. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state income taxes owed.

In addition, under Internal Revenue Code of 1986, as amended ("IRC") Section 382 and Section 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," its ability to use its pre-change NOLs and other pre-change tax attributes (such as tax credit carryforwards) to offset its post-change income may be limited, including as a result of ownership changes that are beyond its control. A Section 382 "ownership change" is generally defined as a greater than 50 percentage point change (by value) in the company's equity ownership by certain "5-percent shareholders" over a rolling three-year period. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. The Company has completed an analysis and determined that ownership changes have occurred under Section 382 in the past, as well as in 2023 due to the Merger.

The Company's deferred tax assets have been reduced by the amount of NOLs and tax credit carryforwards expected to expire unused due to the Section 382 limitation. We may experience subsequent shifts in our stock ownership, some of which are outside of our control. As a result, if we earn net taxable income and determine that an ownership change has occurred and our ability to use our historical NOLs and tax credit carryforwards are materially limited, it will adversely affect our future operating results by effectively increasing our future income tax obligations.

Changes in tax laws or in their implementation may adversely affect our business, operating results, or financial condition.

Changes in tax laws, including changes to tax rates, tax treaties, and regulations or their interpretation, may cause us to experience fluctuations in our tax obligations and effective tax rates and otherwise may adversely affect our business, operating results, or financial condition. For example, on December 22, 2017, the United States government enacted the TCJA, which significantly reformed the Code. The TCJA, as amended by the CARES Act, among other things, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for NOLs to 80% of current year taxable income and the elimination of NOL carrybacks, in each case, for NOLs arising in taxable years beginning after December 31, 2017 (though any such NOLs may be carried forward indefinitely), the requirement for research and experimental ("R&E") expenditures to be capitalized for tax years beginning after December 31, 2021, and the modification or repeal of many other business deductions and credits. In accordance with the TCJA, R&E expenditures under Code Section 174 are required to be amortized over a period of five years for domestic expenses and 15 years for foreign expenses beginning in 2022. As a result, we have capitalized R&E expenditures in our current tax provision. However, recently proposed tax legislation, if enacted, would restore the ability to deduct currently domestic R&E expenditures through 2025 and would retroactively restore this benefit for 2022 and 2023.

Any of these developments or future changes in federal, state, or international tax laws or tax rulings, including the release of regulatory guidance, could adversely affect our effective tax rate and otherwise affect our business, operating results, or financial condition.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future.

There may not be an active trading market for our common stock and our stockholders may not be able to resell their shares of common stock for a profit, if at all.

Prior to the Merger, there had been no public market for shares of Former Enliven capital stock. An active trading market for our shares of common stock may not be sustained. If an active market for our common stock is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

Future sales of shares by existing stockholders could cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, including under the Shelf Registration or the Sales Agreement. Further, if our existing securityholders 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. Approximately 18 million shares became available for sale in the public market 180 days after the closing of the Merger as a result of the expiration of lock-up agreements. All other outstanding shares of common stock, other than shares held by our affiliates, are freely tradable, without restriction, in the public market. In addition, shares of common stock that are subject to outstanding options of the Company will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these shares are sold, the trading price of our common stock could decline.

Our executive officers, directors and principal stockholders will have the ability to control or significantly influence all matters submitted to our stockholders for approval.

As of March 31, 2024, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 79.0% of our voting stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs, for example, the election of directors and approval of any merger, consolidation or sale of all or substantially all of our

assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

We have broad discretion in the use of our cash, cash equivalents and marketable securities and the proceeds from the Former Enliven pre-closing financing and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We have broad discretion over the use of our cash, cash equivalents and marketable securities and the proceeds from the Former Enliven pre-closing financing. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our cash resources.

Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes-Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, could have a material adverse effect on our business and share price.

As a privately held company, Former Enliven was not required to evaluate its internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404 of the Sarbanes-Oxley Act ("Section 404"). Our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

General Risk Factors

Our operations are vulnerable to interruption by flood, fire, earthquakes, power loss, telecommunications failure, terrorist activity, pandemics and other events beyond our control, which could harm our business.

Our office facilities are located in Colorado. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major blizzard, flood, fire, earthquake, power loss, telecommunications failure, terrorist activity, pandemics or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. Also, our CROs and suppliers' facilities are located in multiple locations where other natural disasters or similar events which could severely disrupt our operations, could expose us to liability and could have a material adverse effect on our business. In addition, telecommunication system failures or disruptions could significantly disrupt our operations since our employees are primarily working remotely. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. In addition, concerns about terrorism, the effects of a terrorist attack, political turmoil or an epidemic outbreak could have a negative effect on our operations and the operations of our suppliers, which could harm our business, financial condition and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Other than as previously reported on our Current Reports on Form 8-K, there have been no unregistered sales of equity securities for the current reporting period.

Use of Proceeds from Registered Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

On October 19, 2023, Rahul Ballal, Ph.D., a director, adopted a Rule 10b5-1 trading arrangement providing for the sale from time to time of an aggregate of up to 97,420 shares of our common stock. The trading arrangement is/was intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement is until February 16, 2026, or earlier if all transactions under the trading arrangement are completed.

During our last fiscal quarter, no officers or directors, as defined in Rule 16a-1(f), adopted and/or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” as defined in Regulation S-K Item 408.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
4.1	Form of Pre-Funded Warrant	8-K	001-39247	4.1	March 19, 2024
10.1+*	Sam Kintz Confirmatory Employment Letter, as amended and restated February 29, 2024	10-K	001-39247	10.6	March 14, 2024
10.2+*	Helen Collins Confirmatory Employment Letter, as amended and restated February 29, 2024	10-K	001-39247	10.7	March 14, 2024
10.3+*	Benjamin Hohl Confirmatory Employment Letter, as amended and restated February 29, 2024	10-K	001-39247	10.8	March 14, 2024
10.4+*	Joseph Lyssikatos Confirmatory Employment Letter, as amended and restated February 29, 2024	10-K	001-39247	10.9	March 14, 2024
10.5+*	Anish Patel Confirmatory Employment Letter, as amended and restated February 29, 2024	10-K	001-39247	10.10	March 14, 2024
10.6+	Sam Kintz Change in Control and Severance Agreement, as amended and restated February 29, 2024	10-K	001-39247	10.11	March 14, 2024
10.7+	Helen Collins Change in Control and Severance Agreement, as amended and restated February 29, 2024	10-K	001-39247	10.12	March 14, 2024
10.8+	Benjamin Hohl Change in Control and Severance Agreement, as amended and restated February 29, 2024	10-K	001-39247	10.13	March 14, 2024
10.9+	Joseph Lyssikatos Change in Control and Severance Agreement, as amended and restated February 29, 2024	10-K	001-39247	10.14	March 14, 2024
10.10+	Anish Patel Change in Control and Severance Agreement, as amended and restated February 29, 2024	10-K	001-39247	10.15	March 14, 2024
10.11+	Outside Director Compensation Policy, as amended February 13, 2024	10-K	001-39247	10.16	March 14, 2024
10.12*	Securities Purchase Agreement, dated March 19, 2024, by and among the Company and the Purchasers named therein	8-K	001-39247	10.1	March 19, 2024
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				Filed herewith
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				Filed herewith
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				Furnished herewith
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				Furnished herewith
101.INS	INLINE XBRL Instance Document				Furnished herewith
101.SCH	INLINE XBRL Taxonomy Extension Schema with Embedded Linkbase Documents				Furnished herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				Furnished herewith

\+ Management contract or compensatory plan.
* Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(a)(6).

** The certifications attached as Exhibits 32.1 and 32.2 that accompany this quarterly report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Enliven Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

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.

Enliven Therapeutics, Inc.

Date: May 14, 2024 By: /s/ Samuel Kintz
Samuel Kintz
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 14, 2024 By: /s/ Benjamin Hohl
Benjamin Hohl
Chief Financial Officer
(Principal Financial and Accounting Officer)

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, Samuel Kintz, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Enliven 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(s) 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(s) 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: May 14, 2024

By: /s/ Samuel Kintz
Samuel Kintz
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Benjamin Hohl, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Enliven 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(s) 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(s) 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: May 14, 2024

By: /s/ Benjamin Hohl
Benjamin Hohl
Chief Financial Officer
(Principal Financial and Accounting 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 Enliven Therapeutics, Inc. (the "Company") for the period ending March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Samuel Kintz, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2024

By: /s/ Samuel Kintz
Samuel Kintz
President and 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 Enliven Therapeutics, Inc. (the "Company") for the period ending March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Benjamin Hohl, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2024

By: /s/ Benjamin Hohl
Benjamin Hohl
Chief Financial Officer
(Principal Financial and Accounting Officer)