UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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: 001-40629

CANDEL THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**52-2214851**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
117 Kendrick St, Suite 450 Needham, MA	**02494**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 916-5445

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.01 per share	CADL	The Nasdaq Global 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of May 6, 2024, the registrant had 29,744,731 shares of common stock, $0.01 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (Form 10-Q), including the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contains express or implied forward-looking statements that are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Form 10-Q may include, but are not limited to, statements about:

- the timing and the success of preclinical studies and clinical trials of CAN-2409 and CAN-3110 and any other product candidates;
- the initiation of any clinical trials of CAN-2409 (international non-proprietary name: aglatimagene besadenovec) and CAN-3110 and any other product candidates;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- our ability to conduct successful clinical trials or obtain regulatory approval for CAN-2409 and CAN-3110 or any other product candidates that we may identify or develop;
- the ability of our research to generate and advance additional product candidates;
- the effects of public health crises, outbreaks of an infectious disease or ongoing geopolitical conflicts, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations;
- our ability to establish an adequate safety or efficacy profile for CAN-2409, CAN-3110 or any other product candidates that we may pursue;
- our ability to manufacture CAN-2409, CAN-3110 or any other product candidate in conformity with our specifications and the U.S. Food and Drug Administration’s (FDA) requirements and to scale up manufacturing of our product candidates to commercial scale, if approved;
- the implementation of our strategic plans for our business, any product candidates we may develop and any companion diagnostics;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates any companion diagnostics;
- the rate and degree of market acceptance and clinical utility for any product candidates we may develop;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the period we estimate to be funded by our existing financial resources;
- our ability to establish and maintain collaborations;
- the potential benefits with the continued existence of our license agreement with Mass General Brigham (MGB);
- our financial performance;
- our ability to effectively manage our anticipated growth;
- developments relating to our competitors and our industry, including the impact of government regulation;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals; and
- other risks and uncertainties, including those discussed in Part II, Item 1A - Risk Factors in this Form 10-Q.

In some cases, forward-looking statements can be identified by terminology such as “will,” “may,” “should,” “could,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled “Risk Factors” and elsewhere in this Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those expressed or implied by the forward-looking statements. No forward-looking statement is a promise or a guarantee of future performance.

The forward-looking statements in this Form 10-Q represent our views as of the date of this Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Form 10-Q.

This Form 10-Q may include statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We have not independently verified the information contained in such sources.

SUMMARY OF THE MATERIAL AND OTHER RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties, including those described more fully in Part II, Item 1A - Risk Factors in this Form 10-Q. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- We are a biopharmaceutical company with a limited operating history and we have not generated any revenue from product sales. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years and may never achieve or maintain profitability.
- Substantial doubt exists about our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient additional funding to finance our operations. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate some of our research, clinical trials, product development, or future commercialization efforts.
- We have incurred indebtedness, and we may incur additional indebtedness, which could adversely affect our financial condition.
- Our business is dependent on the success of CAN-2409, CAN-3110 and any other product candidates that we advance into the clinic. All of our product candidates will require additional development before we may be able to seek regulatory approval for and launch a product commercially.
- Our preclinical studies and clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval, and commercialization.
- Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval, if at all.
- Even if we receive marketing approval for our current or future product candidates, our current or future product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.
- The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize CAN-2409, CAN-3110 and future product candidates as expected, and our ability to generate revenue may be materially impaired.
- The FDA's agreement to a Special Protocol Assessment with respect to the study design of our phase 3 clinical trial of CAN-2409 in newly diagnosed localized prostate cancer in intermediate and high-risk patients does not guarantee any particular outcome from regulatory review, including ultimate approval, and may not lead to a successful review or approval process.
- Some of our product candidates are being and may continue to be studied in third-party research and clinical trials sponsored by organizations or agencies other than us, or in investigator-sponsored clinical trials, which means we will have minimal or no control over the conduct of such trials and which may adversely affect our ability to obtain marketing approval or certain regulatory exclusivities.
- Changes in product candidate manufacturing or formulation may result in additional costs or delay.
- Any future public health crisis, outbreaks of an infectious disease or ongoing geopolitical conflicts may have adverse effects on our business and operations.
- If the government or third-party payors fail to provide adequate coverage, reimbursement and payment rates for our product candidates, or if health maintenance organizations or long-term care facilities choose to use therapies that are less expensive or considered a better value, our revenue and prospects for profitability will be limited.
- If the manufacturers upon which we may rely fail to produce our product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.
- The transition of our manufacturing operations to a third-party contract manufacturer may result in further delays or expenses, and we may not experience the anticipated operating efficiencies.
- Our rights to develop and commercialize certain of our product candidates are subject and may in the future be subject, in part, to the terms and conditions of licenses granted to us by third parties. If we fail to comply with our obligations under our current or future intellectual property license agreements or otherwise experience disruptions

to our business relationships with our current or any future licensors, we could lose intellectual property rights that are important to our business.

NOTE REGARDING COMPANY REFERENCES

Unless the context otherwise requires, the terms “Candel Therapeutics,” “the Company,” “we,” “us,” and “our” in this Form 10-Q refer to Candel Therapeutics, Inc. and its consolidated subsidiary.

NOTE REGARDING TRADEMARKS

We own or have rights to various trademarks, service marks and trade names that are used in connection with the operation of our business, including our company name, Candel Therapeutics, our logo, and the names of our CAN-2409™ and CAN-3110™ product candidates. This Form 10-Q may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties’ trademarks, service marks, trade names or products in this Form 10-Q is not intended to and does not imply a relationship with, or endorsement or sponsorship by, us. Solely for convenience, the trademarks, service marks and trade names referred to in this Form 10-Q may appear without the ®, TM or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks and trade names.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

CANDEL THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	MARCH 31, 2024 (Unaudited)	DECEMBER 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 25,713	$ 35,413
Prepaid expenses and other current assets	1,423	1,384
Total current assets	27,136	36,797
Fixed assets, net	2,962	3,206
Lease right of use assets	751	816
Restricted cash	266	266
Other assets	102	116
Total assets	$ 31,217	$ 41,201
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 472	$ 422
Accrued expenses	2,772	4,356
Current portion of term loan payable to a bank	9,767	8,893
Current portion of lease liability	526	513
Total current liabilities	13,537	14,184
Term loan payable to a bank	9,174	11,632
Other long-term debt	781	751
Lease liability, net of current portion	837	973
Warrant liability	909	916
Total liabilities	25,238	28,456
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued or outstanding at March 31, 2024 and December 31, 2023, respectively.	—	—
Common stock, $0.01 par value; 150,000,000 shares authorized at March 31, 2024 and December 31, 2023; 29,470,076 and 29,213,627 shares issued at March 31, 2024 and December 31, 2023, respectively; 29,347,468 and 29,091,019 shares outstanding at March 31, 2024 and December 31, 2023, respectively.	292	290
Treasury stock (at cost)	(448)	(448)
Additional paid-in capital	151,384	149,931
Accumulated deficit	(145,249)	(137,028)
Total stockholders' equity	5,979	12,745
Total liabilities and stockholders' equity	$ 31,217	$ 41,201

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

CANDEL THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	THREE MONTHS ENDED MARCH 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 4,102	$ 5,469
General and administrative	3,800	4,164
Total operating expenses	7,902	9,633
Loss from operations	(7,902)	(9,633)
Other income (expense):		
Grant income	—	12
Interest income	320	711
Interest expense	(646)	(609)
Change in fair value of warrant liability	7	724
Total other income (expense), net	(319)	838
Net loss and comprehensive loss	$ (8,221)	$ (8,795)
Net loss per share, basic and diluted	$ (0.28)	$ (0.30)
Weighted-average common shares outstanding, basic and diluted	29,197,537	28,919,810

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

CANDEL THERAPEUTICS, INC.

Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)
(Unaudited)

	COMMON STOCK		TREASURY STOCK		ADDITIONAL PAID-IN	ACCUMULATED	STOCKHOLDERS'
	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	DEFICIT	EQUITY
Balance, December 31, 2023	29,213,627	$ 290	(122,608)	$ (448)	$ 149,931	$ (137,028)	$ 12,745
Options exercised	146,964	1	—	—	225	$ —	226
Stock-based compensation	—	—	—	—	1,030	—	1,030
Change in fair value of NC Ohio Trust Warrants	—	—	—	—	13	—	13
Sale of common stock, net of issuance costs	109,485	1			185	—	186
Net loss	—	—	—	—	—	(8,221)	(8,221)
Balance, March 31, 2024	29,470,076	$ 292	(122,608)	$ (448)	$ 151,384	$ (145,249)	$ 5,979

	COMMON STOCK		TREASURY STOCK		ADDITIONAL PAID-IN	ACCUMULATED	STOCKHOLDERS'
	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	DEFICIT	EQUITY
Balance, December 31, 2022	29,042,418	$ 290	(122,608)	$ (448)	$ 146,961	$ (99,089)	$ 47,714
Stock-based compensation	—	—	—	—	798	—	798
Change in fair value of NC Ohio Trust Warrants	—	—	—	—	(65)	—	(65)
Net loss	—	—	—	—	—	(8,795)	(8,795)
Balance, March 31, 2023	29,042,418	$ 290	(122,608)	$ (448)	$ 147,694	$ (107,884)	$ 39,652

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

CANDEL THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	THREE MONTHS ENDED MARCH 31,	
	2024	**2023**
Cash Flows from Operating Activities:		
Net loss	$ (8,221)	$ (8,795)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	251	230
Loss on the sale of fixed assets	—	74
Non-cash stock compensation expense	1,043	733
Non-cash lease expense	65	57
Non-cash interest expense	30	26
Change in fair value of warrant liability	(7)	(724)
Accretion of debt discount	83	75
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(39)	(730)
Other assets	14	—
Accounts payable	50	149
Accrued expenses	(1,584)	(1,790)
Deferred income	—	(12)
Lease liability	(123)	(112)
Net cash used in operating activities	**(8,438)**	**(10,819)**
Cash Flows from Investing Activities:		
Purchase of fixed assets	(7)	(138)
Proceeds from the sale of fixed assets	—	157
Net cash (used in) provided by investing activities	**(7)**	**19**
Cash Flows from Financing Activities:		
Proceeds from option exercises	226	—
Proceeds from sale of common stock, net of issuance costs	186	—
Principal payments on term loan	(1,667)	—
Net cash used in financing activities	**(1,255)**	**—**
Net decrease in cash	**(9,700)**	**(10,800)**
Cash, cash equivalents and restricted cash at beginning of period	**35,679**	**70,324**
Cash, cash equivalents and restricted cash at end of period	**$ 25,979**	**$ 59,524**
Supplemental cash flow information:		
Cash paid for interest	$ 549	$ 500
Supplemental disclosures of non-cash information:		
Capital expenditures in accounts payable and accrued expenses	$ —	$ 66

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

1. Organization and Basis of Presentation

Candel Therapeutics, Inc., formerly known as Advantagene, Inc. (the Company), is a clinical stage biopharmaceutical company that was incorporated in Delaware in June 2003. On November 30, 2020, the Company changed its name to Candel Therapeutics, Inc. The Company is focused on developing off-the-shelf viral immunotherapies that elicit an individualized, systemic anti-tumor immune response to help patients fight cancer. The Company's engineered viruses are designed to induce immunogenic cell death through direct viral-mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens and creating a pro-inflammatory microenvironment at the site of injection. This is intended to lead to in-situ vaccination against the injected tumor and uninjected distant metastases. The Company has established two off-the-shelf viral immunotherapy platforms and its two product candidates, CAN-2409 and CAN-3110, are in clinical trials for a number of tumor types. Additionally, the Company and the University of Pennsylvania (UPenn) are collaborating to study the impact of novel viral immunotherapies based on Candel's propriety enLIGHTEN™ Discovery Platform, a systematic, iterative herpes simplex virus based platform leveraging human biology and advanced analytics, to strengthen the effects of UPenn's investigational CAR-T cell therapies in solid tumors.

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

Since inception, the Company has funded its operations primarily with proceeds from the sale of its convertible notes and capital stock and from debt borrowings. The Company has incurred recurring losses since its inception, including a net loss of $8.2 million and $8.8 million for the three months ended March 31, 2024 and 2023, respectively. In addition, as of March 31, 2024, the Company had an accumulated deficit of $145.2 million. The Company expects to continue to generate operating losses and negative cash flows from operations for the foreseeable future.

On August 5, 2022, the Company filed a shelf registration statement on Form S-3 (as amended to date, the Shelf) with the U.S. Securities and Exchange Commission (SEC), which covers the offering, issuance, and sale by us of up to an aggregate of $200.0 million of our common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. We simultaneously entered into a sales agreement with Jefferies LLC, as sales agent, to provide for the issuance and sale by us of up to $75.0 million of our common stock from time to time in "at-the-market" offerings under the Shelf (the ATM Program). The Shelf was declared effective by the SEC on August 12, 2022. As of March 31, 2024, the Company has sold and issued 109,485 shares of common stock under the ATM Program, with total net proceeds of $0.2 million. Subsequent to March 31, 2024, no additional sales have been made under the ATM Program.

The Company's cash and cash equivalents were $25.7 million as of March 31, 2024. In accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC), 205-40, Presentation of Financial Statements - Going Concern, management is required to assess the Company's ability to continue as a going concern for the one-year look forward period following the date that the condensed consolidated financial statements are issued. The Company expects to continue to generate operating losses and negative cash flows from operations. Based on these conditions, the Company has determined that substantial doubt exists regarding its ability to continue as a going concern for the one-year period following the date these condensed consolidated financial statements are issued. To sustain its future operations beyond such one-year period, the Company will require additional funding. The Company expects to finance its cash needs through a combination of public or private equity or debt financings, government grants, and other sources, which may include collaborations, strategic alliances and licensing arrangements with third parties. There is no assurance that the Company will be successful in obtaining sufficient funding on acceptable terms, if at all, and the Company could be forced to delay, reduce, or eliminate some or all of its research, clinical trials, product development or future commercialization efforts, which could materially adversely affect its business prospects or its ability to continue as a going concern.

The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the condensed consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and that contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting standards set by the FASB. The FASB sets generally accepted accounting principles (GAAP) that the Company follows to ensure its financial condition, results of operations, and cash flows are consistently reported. References to GAAP issued by the FASB in these notes to the financial statements are to the FASB ASC. The Company has reclassified certain amounts relating to its prior period results to conform to its current period presentation.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Candel Therapeutics, Inc. and its wholly owned subsidiary Candel Therapeutics Securities Corporation. All intercompany transactions and balances have been eliminated.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision maker, the Company's chief executive officer, views the Company's operations and manages its business as a single operating segment. The Company only operates in the United States.

Emerging Growth Company

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 is (i) 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 condensed consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of March 31, 2024, the condensed consolidated statements of operations for the three months ended March 31, 2024 and 2023, the condensed consolidated statements of stockholders' equity for the three months ended March 31, 2024 and 2023, the condensed consolidated statements of cash flows for the three months ended March 31, 2024 and 2023, and the related interim disclosures are unaudited. These condensed consolidated financial statements include all adjustments necessary, consisting of only normal recurring adjustments, to fairly state the financial position and the results of the Company's operations and cash flows for interim periods in accordance with U.S. GAAP. Interim period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period. The accompanying condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K on file with the SEC.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and related disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. On an ongoing basis, the Company's management evaluates its estimates, which include but are not limited to management's judgments of accrued expenses, valuation of stock-based option awards, valuations of warrants, and income taxes. Actual results could differ from those estimates.

Restricted Cash

The Company had $0.3 million of restricted cash as of both March 31, 2024 and December 31, 2023, which represents cash held as a security deposit under the terms of the Company's Needham, Massachusetts facility lease.

Recently Issued Accounting Standards

In October 2023, the FASB issued ASU 2023-06, Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative, which modifies the disclosure or presentation requirements related to a variety of FASB Accounting Standard Codification topics. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K is effective, with early adoption prohibited. If by

June 30, 2027, the SEC has not removed the applicable requirement from Regulation S-X or Regulation S-K, the pending content of the associated amendment will be removed from the Codification and will not become effective for any entities. The Company is currently evaluating the potential impact that ASU 2023-06 may have on its condensed consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting: Improvements to Reportable Segment Disclosures, which amends guidance in ASC 280, Segment Reporting The amendments in this ASU expand segment disclosure requirements, including new segment disclosure requirements for entities with a single reportable segment, among other disclosure requirements. The ASU's amendments are effective for public business entities for annual periods beginning after December 15, 2023. Early adoption is permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2023-07 may have on its condensed consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Improvements to Income Tax Disclosures, which amends the guidance in ASC 740, Income Taxes. The ASU is intended to improve the transparency of income tax disclosures by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. The ASU's amendments are effective for public business entities for annual periods beginning after December 15, 2024. Early adoption is permitted. Adoption can be either prospectively or retrospectively applied, and the Company will adopt this ASU on a prospective basis. The Company is currently evaluating the potential impact that ASU 2023-09 may have on its condensed consolidated financial statements and related disclosures.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	FAIR VALUE MEASUREMENTS AS OF MARCH 31, 2024 USING:			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Liabilities:				
Warrant liability	—	—	909	909
Total	$ —	$ —	$ 909	$ 909

	FAIR VALUE MEASUREMENTS AS OF DECEMBER 31, 2023 USING:			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Liabilities:				
Warrant liability	—	—	916	916
Total	$ —	$ —	$ 916	$ 916

The following table provides a roll forward of the aggregate fair values of the Company's warrant liability, for which fair value is determined by Level 3 inputs (in thousands):

	SERIES B WARRANT LIABILITY
Balance at December 31, 2023	$ 916
Change in fair value	(7)
Balance at March 31, 2024	$ 909

4. Fixed Assets, Net

Fixed assets, net consisted of the following (in thousands):

	MARCH 31, 2024	DECEMBER 31, 2023
Laboratory equipment	$ 1,213	$ 1,209
Manufacturing equipment	733	730
Furniture and fixtures	159	159
Networking and computer equipment	88	88
Leasehold improvements	3,109	3,109
Total fixed assets	$ 5,302	$ 5,295
Less: accumulated depreciation	(2,340)	(2,089)
Fixed assets, net	$ 2,962	$ 3,206

Depreciation expense was $0.3 million and $0.2 million for the three months ended March 31, 2024 and 2023, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	MARCH 31, 2024	DECEMBER 31, 2023
Payroll and employee related expenses	$ 1,192	$ 2,017
Third-party research and development expenses	749	1,811
Professional fees and other	831	528
	$ 2,772	$ 4,356

6. Term Loan

On February 24, 2022, the Company entered into a four-year loan and security agreement (the Loan Agreement) with Silicon Valley Bank (SVB) pursuant to which SVB has agreed to provide term loans to the Company in an aggregate principal amount of up to $25.0 million. The Company borrowed $20.0 million upon entering into the Loan Agreement. The Company could have borrowed up to an additional aggregate principal amount not to exceed $5.0 million, at any time on or prior to December 31, 2022, upon achievement of all of the following milestones, inclusively: (a) positive phase 2 clinical activity data from the Company's CAN-2409 NSCLC clinical trial, (b) dosing of its first patient in its phase 3 CAN-2409 high-grade glioma clinical trial, and (c) receipt on or prior to December 31, 2022, of net cash proceeds in an amount equal to at least $75.0 million from the issuance and sale of equity securities to investors acceptable to SVB. The Company did not borrow any of the additional aggregate principal amount on or prior to December 31, 2022. The term loan is secured by substantially all of the Company's properties, rights and assets, except for its intellectual property, which is subject to a negative pledge under the Loan Agreement.

The term loans bear interest at a floating rate per annum equal to the greater of (A) 5.75% and (B) the prime rate (as published in the money rates section of The Wall Street Journal) plus 2.50%. The Company is required to make monthly interest payments, and commencing on February 1, 2024, 24 consecutive installments of principal plus monthly payments of accrued interest. The term loans mature on January 1, 2026. Upon repayment in full of the term loans, the Company will be required to pay a final payment fee equal to 4.50% of the original principal amount of any funded term loan being repaid. The Loan Agreement permits voluntary prepayment of all, but not less than all, of the SVB term loans, subject to a prepayment premium of 1% to 3% based upon the timing of the repayment.

During each of the three months ended March 31, 2024 and 2023, the Company recorded interest expense relating to the Loan Agreement of $0.6 million. The weighted average effective interest rate as of March 31, 2024 was 11.40%.

The Company incurred $89,000 of debt issuance costs and will incur a $0.9 million final payment fee, which were recorded as debt discount and are being amortized over the term of the Loan Agreement. The scheduled principal payments and net carrying amount of the term loan are as follows (in thousands):

YEAR ENDING DECEMBER 31,		
2024 (remaining nine months)	$	7,500
2025		10,000
2026		833
Total principal		18,333
Final payment fee		900
Less: debt discount		(989)
Accretion of debt discount		697
Net carrying amount		18,941
Less current portion		(9,767)
Long-term portion	$	9,174

The carrying value of the Company's term loan approximates fair value.

7. Other Long-Term Debt

Periphagen Note

On December 9, 2019, the Company entered into a series of asset purchase agreements with Periphagen, Inc. (Periphagen), a biopharmaceutical company focused on the development of gene therapy vectors. Under the terms of the asset purchase agreements, the Company assumed a $1.0 million promissory note bearing a contractual interest rate of 2% compounded annually, with the outstanding balance and accrued interest due upon maturity in November 2027, with no interim installments due. The estimated market rate for the Company for an unsecured loan with a maturity in November 2027 was determined to be 15.83% as of December 9, 2019. Although the Company does not have a public credit rating, management estimates a CCC credit rating based on the Company's financial position and stage of development. Using the commensurate rate for a CCC rated company and based on the amount due at maturity, the present value of the future cash outflow was determined to be $0.4 million at the transaction date. As of March 31, 2024, the carrying value of the note is $0.8 million. The carrying value of the note approximates fair value. Upon maturity, the Company will pay Periphagen $1.4 million for the outstanding balance and accrued interest due.

8. Lease

On February 4, 2019, the Company signed a lease agreement for its corporate headquarters at 117 Kendrick Street in Needham, Massachusetts. The facility consists of a 15,197 square foot property which houses the corporate, clinical, laboratory and manufacturing operations for the Company. The lease term ends on August 31, 2026.

For each of the three months ended March 31, 2024 and 2023, the Company recorded $0.1 million of operating lease cost and for the three months ended March 31, 2024 and 2023, the Company has recorded $38,000 and $49,000, respectively, of variable lease cost. The total lease expense for each of the three months ended March 31, 2024 and 2023 was $0.1 million.

Cash paid for amounts included in the lease liability for each of the three months ended March 31, 2024 and 2023 was $0.1 million.

	THREE MONTHS ENDED MARCH 31,	
Other Information	**2024**	**2023**
Operating cash flows used for operating leases	$ 148	$ 144
Weighted-average remaining lease term (years)	2.4	3.4
Weighted-average incremental borrowing rate	7.02%	7.02%

The future lease payments under non-cancelable leases at March 31, 2024, are as follows (in thousands):

2024	450
2025	613
2026	415
Total future lease payments	1,478
Less: imputed interest	(115)
Total lease liability	$ 1,363

9. Common Stock

Common Stock

Common shares are voting and dividends may be paid when, as and if declared by the board of directors.

Common Stock Reserved

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

	MARCH 31, 2024	DECEMBER 31, 2023
Stock options outstanding	5,112,673	5,666,621
Unvested restricted stock	2,306,889	2,526,432
Shares available for future grant under stock option plan	2,042,216	252,053
Warrants	7,507,708	7,507,708
	16,969,486	15,952,814

Shelf Registration and At-the-Market Offerings

On August 5, 2022, the Company filed the Shelf with the SEC, which covers the offering, issuance, and sale by us of up to an aggregate of $200.0 million of our common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. We simultaneously entered into a sales agreement with Jefferies LLC, as sales agent, to provide for the issuance and sale by us of up to $75.0 million of our common stock from time to time in “at-the-market” offerings under the Shelf. The Shelf was declared effective by the SEC on August 12, 2022. As of March 31, 2024, the Company has sold and issued 109,485 shares of common stock under the ATM Program, with total net proceeds of $0.2 million. Subsequent to March 31, 2024, no additional sales have been made under the ATM Program.

10. Warrants

The Company has the following warrants outstanding for the purchase of common stock as of March 31, 2024 and December 31, 2023:

WARRANTS	SHARES OF COMMON STOCK SUBJECT TO WARRANTS		EXERCISE PRICE PER SHARE	EXPIRATION DATES
Series B Warrants	3,672,484	$	6.81	November 2025
Conditional Series B Warrants	3,672,484	$	6.81	November 2025
NC Ohio Trust	162,740	$	1.46	March 2029

Series B Warrants

In connection with the November 13, 2018 issuance of Series B convertible preferred stock (the Series B Preferred), the Company issued to the purchaser of the Series B Preferred warrants to purchase 3,672,484 shares of common stock for $6.81 per share (the Series B Warrants), which became fully exercisable upon issuance. The Series B Warrants contain provisions allowing cashless exercise.

In addition, the Company issued to the same stockholder additional five-year warrants for the purchase of 3,672,484 shares of common stock for $6.81 per share (the Conditional Series B Warrants), which become exercisable in the event that the Company completes a future financing that meets certain financial milestones or achieves certain share prices as follows:

- 918,121 shares vest upon (1) a financing event effected through the sale of our equity securities to third parties resulting in at least $20,000,000 in gross proceeds, with a per share price of $12.47, or (2) an average market price (determined over a consecutive 10-day period) of $12.47 per share;
- an additional 918,121 shares vest upon (1) a financing event with a price per share of $13.20, or (2) an average market price (determined over a consecutive 10-day period) of, $13.20 per share;
- an additional 918,121 shares vest upon (1) a financing event with a per share price of $13.94, or (2) an average market price (determined over a consecutive 10-day period) of, $13.94 per share; and
- an additional 918,121 shares vest upon (1) a financing event with a per share price of $14.68, or (2) an average market price (determined over a consecutive 10-day period) of, $14.68 per share.

On June 24, 2021, the Company's board of directors approved and on July 14, 2021 the stockholders approved, effective upon the closing of the Company's initial public offering, an amendment to the terms of the Series B Warrants and the Conditional Series B Warrants to extend the expiration date from November 2023 to November 2025. In addition, the exercise period for the Conditional Series B Warrants was amended such that in the event the future financing milestones or certain share price targets described above are achieved, the Conditional Series B Warrants can only be exercised in conjunction with the sale of the Company, on a cash or cashless exercise basis, or otherwise in November 2025 through a cashless exercise.

The Company recorded the Series B Warrants as a component of stockholder's equity at the time of issuance at their estimated fair value of $2.1 million and recorded the Conditional Series B Warrants as a liability on the condensed consolidated balance sheet as the number of shares used to calculate the settlement is not a fixed number of shares. The Conditional Series B Warrants are remeasured to their fair value at each reporting date with changes in the fair value recognized as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. The Company will continue to recognize changes in the fair value of the Conditional Series B Warrants until each Conditional Series B Warrant is exercised, expires or qualifies for equity classification. The warrant liability fair value was $0.9 million as of both March 31, 2024 and December 31, 2023.

NC Ohio Trust Warrants

On March 20, 2019, the Company established the NC Incorporated Ohio Trust, an irrevocable trust funded by the Company. The beneficiary in the trust agreement has provided past services to the Company for more than 15 years and is a non-employee. The warrant provides the beneficiary the right to purchase 162,740 shares of the Company's common stock, $0.01 par value at an exercise price of $1.46 per share, subject to adjustments as specified in the warrant agreement. The Company recognizes the warrants as compensation expense within the condensed consolidated statement of operations and comprehensive loss when the warrants are granted or at the service inception date if the service inception date precedes the grant date. In the period in which the grant date occurs, cumulative compensation cost shall be adjusted to reflect the cumulative effect of measuring compensation cost based on the fair value at the grant date rather than the fair value previously used at the service inception date or subsequent reporting dates. As of March 31, 2024 and December 31, 2023, a grant date was not established as there was not a mutual understanding of key terms. The Company remeasures the fair value of the award at

each reporting date, as the service date preceded the grant date. The value of the warrants for 162,740 shares of common stock was $0.2 million as of both March 31, 2024 and December 31, 2023, and was recorded as stock compensation expense within research and development expense and a credit to stockholders' equity in the condensed consolidated financial statements.

11. Stock Options, Restricted Stock and Stock-Based Compensation

Equity Incentive Plans

The Company's 2015 Stock Plan, as amended, (the 2015 Plan) provides for the Company to sell or issue common shares or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company. The 2015 Plan is administered by the board of directors and exercise prices, vesting and other restrictions are determined at its discretion. All stock option grants are non-statutory stock options except option grants to employees intended to qualify as incentive stock options under the Internal Revenue Code of 1986, as amended. Incentive stock options may not be granted at less than the fair market value of the Company's common stock on the date of grant, as determined in good faith by the board of directors at its sole discretion. Nonqualified stock options may be granted at an exercise price established by the board of directors at its sole discretion and the vesting periods may vary. Vesting periods are generally four years and are determined by the board of directors. Stock options become exercisable as they vest. Options granted under the 2015 Plan expire no more than ten years from the date of grant. As of March 31, 2024, there are no shares available for grants under the 2015 Plan and the 2015 Plan continues to govern the terms and conditions of the outstanding awards under the 2015 Plan.

On July 14, 2021, the Company's 2021 Equity Incentive Plan (the 2021 Plan) was approved by the Company's stockholders, and became effective upon completion of the IPO and serves as the successor to the 2015 Plan. 6,645,259 shares of common stock are reserved under the 2021 Plan, of which 2,042,216 shares remain available for future grants as of March 31, 2024.

Stock Options

Stock option activity is summarized as follows:

	NUMBER OF STOCK OPTIONS	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (IN YEARS)	AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding as of December 31, 2023	5,666,621	$ 2.47	6.61	
Granted	67,500	1.59		
Exercised	(146,964)	1.54		
Cancelled, forfeited or expired	(474,484)	3.42		
Outstanding as of March 31, 2024	5,112,673	$ 2.40	6.66	$ 378
Exercisable as of March 31, 2024	3,500,102	$ 2.41	5.80	$ 133
Unvested as of March 31, 2024	1,612,571	$ 2.37	8.53	$ 245

The 2015 Plan, permits participants to use common stock they previously acquired to pay for the exercise of stock options based upon the fair value on the date of exercise. In connection with the exercise of a stock options to purchase 306,518 shares of our common stock at an exercise price of $1.46, option holders tendered 122,608 shares of our common stock previously acquired in consideration of the full aggregate exercise price in accordance with the terms of the option and the 2015 Plan. The shares tendered are recorded as treasury stock within the Company's condensed consolidated financial statements at March 31, 2024.

The fair value of stock options granted was estimated on the grant date using the Black-Scholes option pricing model based on the following assumptions:

	THREE MONTHS ENDED MARCH 31,	
	2024	2023
Expected option life (years)	6.08	6.08
Risk-free interest rate	4.21% - 4.27%	3.58% - 4.13%
Expected volatility	99.30% - 99.45%	91.33% - 92.25%
Expected dividend yield	0%	0%

The total intrinsic value of stock options vested during each of the three months ended March 31, 2024 and 2023 was zero.

Restricted Stock Units

Under the terms of the restricted stock unit agreements covering the common stock, shares of common stock related to restricted stock units are subject to time-based vesting. The restricted stock units will immediately be forfeited to the Company if the relationship between the recipient and the Company ceases.

Restricted stock activity is summarized as follows:

	NUMBER OF SHARES	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE
Unvested at December 31, 2023	2,526,432	$ 1.06
Granted	—	$ —
Vested	—	$ —
Forfeited	(219,543)	$ 1.13
Unvested at March 31, 2024	2,306,889	$ 1.06

The aggregate fair value of restricted stock units that vested during each of the three months ended March 31, 2024 and 2023 was zero.

Stock-Based Compensation

Stock-based compensation expense for the three months ended March 31, 2024 and 2023 was classified in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	THREE MONTHS ENDED MARCH 31,	
	2024	2023
Research and development	$ 553	$ 311
General and administrative	490	422
Total stock-based compensation expense	$ 1,043	$ 733

As of March 31, 2024, total unrecognized compensation cost related to unvested stock-based awards was $4.4 million, which is expected to be recognized over a weighted average period of 2.30 years.

12. Exclusive Licensing Agreement with a Related Party

In March 2014, the Company entered into an exclusive licensing agreement with Ventagen, LLC (Ventagen) which provides Ventagen the right to develop products for commercial sale and distribution within Mexico, Belize, Guatemala, Honduras, El Salvador, Costa Rica, Nicaragua, Panama, Colombia, and Bolivia (the Territory). Ventagen paid the Company $1.0 million upon the signing of the agreement and agreed to a fixed future payment to the Company of $2.5 million. The future payment will be made upon the achievement of $5.0 million of sales of an approved product by Ventagen and is subject to reduction if Ventagen's costs to develop an approved product exceeds $4.0 million. In addition to the upfront payment and the future payment, Ventagen agreed to purchase from the Company all manufactured product that is required for clinical or commercial purposes at a price of cost plus 25% of the wholesale price of the approved product, subject to a minimum or maximum price. In the event the Company is unable or unwilling to manufacture supply under the terms of the agreement, Ventagen has the right to manufacture its own supply and will be required to pay a fixed fee per dose sold. The Company also agreed to provide certain services to Ventagen related to Ventagen's development plan. Stockholders of the Company own 49.5% of the voting stock of Ventagen, including 47% by the Company's founders who are currently significant stockholders of the Company, and trusts for the benefit of their children.

The Company had completely recognized the $1.0 million upfront license fee as research and development service revenue as of December 31, 2022.

13. Technology License Agreement

On January 20, 2018 the Company entered into an exclusive option agreement (Option Agreement) with MGB. Pursuant to the Option Agreement, the Company has obtained the exclusive right from MGB to negotiate an exclusive license to make, develop and commercialize rQNestin, a genetically modified oncolytic herpes simplex virus for the treatment of certain types of cancers. Pursuant to the Option Agreement, the Company will support a clinical trial to be conducted at MGB pursuant to the terms of a clinical trial agreement to be negotiated and the Company has committed to remitting $0.8 million in support of such clinical trial over the course of approximately three years. Upon execution of the Option Agreement, the Company remitted a non-refundable fee of $40,000 to MGB to be applied toward the Company's on-going obligations to reimburse patent expenses. During the three

months ended March 31, 2024 and 2023, the Company did not expense any startup and patient fees for clinical trials performed by MGB.

On September 15, 2020, the Company exercised the Option Agreement with MGB and entered into an exclusive worldwide patent license agreement with MGB (the MGB License). In connection with the MGB License, the Company paid a fee of $0.1 million and agreed to reimburse patent costs incurred by MGB, including $0.1 million paid at the time of entering into the MGB License. Prior to the first commercial sale, the Company is required to pay MGB an annual license fee of $50,000 beginning following the fourth anniversary of the effective date. The MGB License contains cumulative milestone payments equaling a maximum amount of $39.0 million upon the achievement of various clinical, commercial and sales milestones of both primary and secondary products. Following the first commercial sale, the Company is required to pay royalties to MGB, which are paid at an increasing rate as net sales increase, ranging from low single digits to high single digits. In addition, after the first commercial sale, the Company is required to pay MGB a pre-determined fixed annual minimum royalty, which amount may be credited against earned royalties starting in the fourth year following the first commercial sale. The Company also agreed to pay a single digit royalty rate on net sales of any derived products.

14. Commitments and Contingencies

Guarantees

The Company has identified the guarantees described below as disclosable, in accordance with ASC 460, *Guarantees*.

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that should limit its exposure and enable it to recover a portion of any future amounts paid.

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. Such indemnification obligations are usually in effect from the date of execution of the applicable agreement for a period equal to the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain.

The Company leases office space under a noncancelable operating lease expiring in 2026. The Company has standard indemnification arrangements under this lease that require it to indemnify the landlord against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation, or nonperformance of any covenant or condition of the lease.

As of March 31, 2024, the Company had not experienced any losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves have been established.

Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. On December 15, 2022, Periphagen notified us by letter of its claim that we have failed to use commercially reasonable efforts to complete a human proof of concept clinical trial of an NT-3 Asset under an Exclusive License Agreement dated December 9, 2019 between us and Periphagen (the Periphagen License Agreement). On January 13, 2023, we filed a demand for arbitration against Periphagen with the American Arbitration Association, seeking a declaration that Periphagen's December 15 letter failed to comply with the dispute and escalation provisions in the Periphagen License Agreement. On March 10, 2023, Periphagen filed its answer and counterclaims to our demand for arbitration. In its counterclaims, Periphagen sought a declaration that we have not used commercially reasonable efforts to complete a human proof of concept clinical trial of the NT-3 Asset and a declaration that any further extension of time would not be scientifically or commercially reasonable. We denied Periphagen's counterclaims.

On June 7, 2023, the parties entered into an amendment to the Exclusive License Agreement that resolved the dispute and resulted in termination of the arbitration without any financial impact.

We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

15. Net Loss Per Share

Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

	THREE MONTHS ENDED MARCH 31,	
Numerator:	**2024**	**2023**
Net loss	$ (8,221)	$ (8,795)
Denominator:		
Weighted-average shares of common stock outstanding – basic and diluted	29,197,537	28,919,810
Net loss per share – basic and diluted	$ (0.28)	$ (0.30)

The Company's potentially dilutive securities have been excluded from the computation of dilutive net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same.

The Company excluded the following potential shares of common stock from the computation of diluted net loss per share because including them would have had an anti-dilutive effect.

	AS OF MARCH 31,	
	2024	**2023**
Outstanding warrants for common stock	7,507,708	7,507,708
Outstanding stock options (as converted to common stock)	5,112,673	5,479,355
Unvested restricted stock	2,306,889	612,366
	14,927,270	13,599,429

16. Corporate Restructuring

In November 2023, the Company's board of directors authorized a restructuring plan to focus on continuation and expansion of development of CAN-3110 as well as the enLIGHTEN™ Discovery Platform, which resulted in a reduction of the Company's workforce by approximately 45%. Each affected employee's separation occurred in December 2023. As a result, the Company incurred costs of $0.7 million related to severance benefits for the affected employees, including severance payments and limited reimbursement of medical insurance premiums. The restructuring plan was completed in the first quarter of 2024 when the final severance payments of $46,000 were made.

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 condensed and consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q (Form 10-Q). Some of the information contained in this discussion and analysis contains forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk factors" in this Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described below.

Overview

We are a clinical stage biopharmaceutical company focused on developing off-the-shelf viral immunotherapies that elicit an individualized, systemic anti-tumor immune response to help patients fight cancer. Our engineered viruses are designed to induce a systemic anti-tumor response due to immunogenic cell death through direct viral-mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens and creating a pro-inflammatory microenvironment at the site of injection. This is intended to lead to in-situ vaccination against the injected tumor and uninjected distant metastases. Our viral immunotherapy approach utilizes intratumoral administration of genetically engineered viruses to induce tumor cell death and elicit a systemic anti-tumor response. Local delivery enables us to achieve these effects while aiming to minimize systemic toxicity. The immune cells induced by these viral immunotherapies are believed to target patients' specific tumor antigens, potentially improving responses in immunologically "hot" tumors while at the same time infiltrating the tumor microenvironment, transforming non-inflamed "cold" tumors with limited immune response into "hot" tumors. While our product candidates are administered directly into the tumor, we have observed systemic immune response in our preclinical studies and clinical trials that may indicate the potential of our product candidates to induce systemic immune response against distal, uninjected tumors, also known as an "abscopal" effect.

We believe viral immunotherapy is among the most promising cancer treatment modalities today. Our goal is to further improve patient outcomes through viral immunotherapies by selecting the optimal vector, specific transgenes and clinical indications for each tumor type while optimizing product candidate attributes, such as high-titer formulation, intratumoral administration to induce systemic anti-tumor immunity, and storage conditions that could potentially lower logistical barriers for patients and clinicians.

We have established two clinical off-the-shelf viral immunotherapy platforms based on novel, genetically modified adenovirus and herpes simplex virus (HSV) constructs, respectively.

Our most advanced product candidate, CAN-2409, is an off-the-shelf adenovirus product candidate which is administered in conjunction with the prodrug, valacyclovir, that has generated promising clinical activity across a range of solid tumor indications. CAN-2409 is currently being studied in the following ongoing clinical trials:

- *Prostate Cancer*
  - A pivotal phase 3 randomized, triple-blinded and placebo-controlled clinical trial in the United States under a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA) evaluating 711 evaluable patients with newly diagnosed, localized prostate cancer who have an intermediate or high-risk for progression. We completed enrollment of this trial in September 2021, and we expect to report topline data in the fourth quarter of 2024.
  - A phase 2 randomized, double blind, placebo-controlled clinical trial in the United States evaluating 187 patients with low-to-intermediate risk, localized prostate cancer undergoing active surveillance. We completed enrollment of this trial in May 2019, and we expect to report topline data in the fourth quarter of 2024.
- *Non-Small Cell Lung Cancer (NSCLC)*
  - An open-label phase 2 clinical trial in the United States evaluating CAN-2409 plus valacyclovir in combination with continued PD-(L)1 checkpoint inhibitors in approximately 80 patients with stage III/IV NSCLC who have inadequate response to front line PD-(L)1 checkpoint inhibitor treatments. In April 2023, we announced that the FDA granted fast track designation for CAN-2409 plus valacyclovir in combination with pembrolizumab in order to improve survival or delay progression in patients with stage III (not candidates for curative intent) or stage IV NSCLC, who are resistant to first line PD-(L)1 inhibitor therapy and who do not have activating molecular driver mutations or have progressed on directed molecular therapy. These patients historically have had an expected median overall survival (mOS) of <12 months (Reckamp K et al. J Clin Onc 2022;40:2295-2306). The aim of the CAN-2409 immunotherapy antitumor strategy is to raise the tail on the survival curve by increasing the number of long survivors beyond 10-14 months in patients treated with two CAN-2409 injections.
  - In 2022, we presented data from this phase 2 clinical trial where patients who received two administrations of CAN-2409 plus prodrug and completed the 12-week treatment window demonstrated: 1) increased infiltration of CD8+ cytotoxic tumor infiltrating lymphocytes in the tumor microenvironment, systemic expansion of effector T cells and increased soluble granzyme B levels in peripheral blood, 2) favorable changes in the trajectory of tumor progression, 3) decreased tumor size of target lesions in most patients, and 4) reduced size of

uninjected tumor lesions (Aggarwal C et al. Abstract #9037 ASCO June 2022 and Aggarwal C et al. Candel Virtual R&D Day, December 2022). These data were further supported in an update released September 2023, based on a data cutoff of August 1, 2023:

▪40 patients across Cohort 1 (stable disease at enrollment; n=5) and Cohort 2 (progressive disease at enrollment; n=35) were evaluable, as they received two courses of CAN-2409 plus valacyclovir and completed the 12-week treatment window.

▪While overall survival was not yet mature, we observed an encouraging number of long survivors. We believe that CAN-2409 may induce a new state of functional immunosurveillance and durable disease control in a subset of the patients.

▪Of the 40 evaluable patients, 15 patients had lived ≥ 12 months; of these, 10 patients had lived > 18 months, of whom 70% (7/10) were alive as of last follow up. All 4 patients (100%) with overall survival > 24 months were alive at last follow up, with the longest reaching 31.7 months.

▪An additional 18 out of the 40 evaluable patients were also alive but had not yet reached 12 months of follow up.

▪Notably, many patients treated with CAN-2409 had long survival (≥ 12 months) despite having disease features generally associated with advanced disease and reduced likelihood to benefit from immune checkpoint inhibitor therapy, such as low or negative PD-(L)1 expression, including:

•Amongst patients alive ≥ 12 months with known PD-(L)1 status (14/15), 93% had negative or low PD-(L)1 score (<1 or between 1-49).

•Advanced disease with stage IV in 73% (11/15), lymph node involvement in 73% (11/15), pleural effusion in 40% (6/15), bone metastases in 27% (4/15), adrenal metastases in 20% (3/15), brain metastases in 13% (2/15), liver metastases in 7% (1/15), involvement of 3 or more organs in 13% (2/15), and Eastern Cooperative Oncology Group performance status 1 in 40% (6/15).

▪There was a significant increase observed in activated central memory, effector-memory, effector T cells, and natural killer (NK) cells after CAN-2409 treatment. These include CD8+Ki67+IFNg+ T cells, CD8+ granzyme B+Ki67+ T cells, CD56+CD16+granzyme B+ NK cells, and gd+ T cells. We also observed an increase in memory B cells after CAN-2409 treatment.

▪We observed an increase in effector/cytotoxic T cells and NK cells in peripheral blood after the second CAN-2409 administration associated with subsequent improved survival (≥ 12 months).

▪We continued to observe a favorable safety/tolerability profile after CAN-2409 treatment in NSCLC. There were no dose limiting toxicities or grade 4 or greater treatment related adverse events. Grade 3 treatment related adverse events were reported in < 10% of patients receiving at least one dose of CAN-2409 (safety population), which we believe compares favorably to current standard of care (SoC) options.

oIn April 2024, we announced the acceptance of an abstract at the American Society of Clinical Oncology (ASCO) Annual Meeting, where we will present topline overall survival data for Cohort 2 in June 2024.

•*Pancreatic Cancer*

oWe have initiated a randomized phase 2 clinical trial in the United States evaluating CAN-2409 in borderline resectable and locally advanced pancreatic adenocarcinoma. In March 2023, in connection with our cost management and dynamic portfolio management initiatives, we elected to pause new enrollment in this randomized phase 2 clinical trial, subject to additional funding. Despite the pause in new patient enrollment, we presented initial positive interim overall survival and immunological biomarker clinical data at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in the fourth quarter of 2023. In December 2023, we announced that the FDA granted fast track designation for CAN-2409 plus valacyclovir for the treatment of patients with pancreatic ductal adenocarcinoma (PDAC) to improve overall survival. In April 2024, we announced updated positive overall survival data and also announced that the FDA has granted Orphan Drug Designation for CAN-2409 for the treatment of pancreatic cancer.

oIn a previous phase 1b trial, a statistically significant increase in the number of CD8+ tumor infiltrating lymphocytes was observed. Initial positive phase 2 data revealed notable improvements in patients with borderline resectable PDAC following CAN-2409 plus prodrug together with SoC chemoradiation; the following data were disclosed as of the March 29, 2024 data cutoff:

▪Clinical data highlights:

•Prolonged and sustained survival was observed after experimental treatment with CAN-2409 in patients with borderline resectable PDAC.

•Estimated mOS was 28.8 months in the CAN-2409 group versus only 12.5 months in the control group.

•At 24 months, a survival rate of 71.4% was observed in CAN-2409 treated patients, after SoC chemoradiation and prior to surgery, versus only 16.7% in the control group. At 36 months, a survival rate of 47.6% was estimated in patients who received CAN-2409, together with SoC chemoradiation prior to surgery, versus only 16.7% in the control group.

•Importantly, 4 out of 7 patients who received CAN-2409 were still alive at the time of data cutoff, with 2 patients surviving more than 50.0 months from enrollment. Only 1 out of 6 patients, randomized to control SoC chemotherapy, remained alive at data cutoff (alive at 50.6 months).

▪Biomarker data analysis demonstrated:

•Consistent and robust activation of immune response after dosing with CAN-2409.

•In pancreatic tissue of patients treated with CAN-2409 plus prodrug together with SoC (but not SoC alone), dense aggregates of CD8+ granzyme B positive cytotoxic T cells, dendritic cells, and B cells were observed in the tumor microenvironment.

•Increased levels of soluble granzymes B and H as well as pro-inflammatory cytokines, including IFN-γ, were observed in peripheral blood after CAN-2409 treatment, but not after SoC.

▪Safety analysis:

•CAN-2409 was associated with a favorable safety/tolerability profile.

•Addition of CAN-2409 regimen to SoC was generally well tolerated, with no dose-limiting toxicities, including no cases of pancreatitis.

Our lead HSV-based product candidate, CAN-3110, is currently in an ongoing investigator-sponsored phase 1b clinical trial in our initial target indication of recurrent high-grade glioma (HGG). These patients have failed SoC treatment and have a poor prognosis (expected overall survival < 6-9 months). In February 2024, we announced that the FDA granted fast track designation for CAN-3110 for the treatment of patients with recurrent HGG to improve overall survival. Initial overall survival data from this clinical trial was presented in an oral presentation at the ASCO Annual Meeting in June 2021, and additional biomarker data was reported in an oral presentation at the Society for Neuro-Oncology Annual Meeting in November 2021. During our Research and Development Day in December 2022, we presented updated data demonstrating that CAN-3110 was well tolerated with no observed dose-limiting toxicity; achieved 11.6 months mOS with a single dose; and showed evidence of persistent herpes simplex virus 1 (HSV-1) antigen and HSV-1 replication consistent with mechanism of action as well as robust evidence of immune activation. In May 2023, we presented clinical and biomarker data from this ongoing clinical trial in an oral presentation at the American Society of Gene & Cell Therapy (ASGCT) Annual Meeting where we reported mOS in arm A (n=41) ongoing at 11.8 months and mOS in arm B (n=9) ongoing at 12.0 months as of the April 20, 2023 data cutoff. Safety and tolerability data reported no dose-limiting toxicities in both arm A and arm B. In October 2023, we jointly published an article in *Nature* that reported extended survival associated with immune activation in patients with recurrent HGG treated with CAN-3110. Notably, new data reported an increased survival in 66% of patients with positivity for anti-HSV1 antibodies (mOS of 14.2 months). Immune status was positively associated with survival both in patients with pre-existing HSV1 antibodies (pre-treatment) and in 33% of patients that, while negative at baseline, developed anti-HSV1 antibodies after a single injection of CAN-3110. Clinical responses were observed in both injected and uninjected lesions in patients with multifocal disease. Significant tumor responses in both arm A and arm B were observed, with continued reduction in tumor volume in a patient in arm B approximately one year after CAN-3110 treatment. Clinical response for this patient, in follow-up as of data cutoff, continued without additional treatment. Analysis of post-treatment samples demonstrated evidence of persistent HSV antigen expression and replication in both injected and uninjected tumor tissue associated with CD8+ T cell infiltration. The extent of immune activation, measured by gene profiling and quantification of immune cells in post-treatment specimens, was associated with the presence of anti-HSV1 antibodies and survival. Survival was also associated with the diversity of the T cell repertoire in circulating T cells, suggesting that patients treated with CAN-3110 were able to mount a diverse immune response against the virus and tumor antigens released during the oncolytic process had improved survival.

We are conducting an extension of the clinical trial known as arm C, in which patients with recurrent HGG will receive a repeat dosing regimen of CAN-3110 (up to six injections over four months). Clinical data from arm C will help evaluate whether multiple injections can increase mOS. This clinical trial extension is supported by the Break Through Cancer foundation. In March 2024, we announced, during the 5th Glioblastoma Drug Development Summit in Boston, that six patients have been treated with multiple injections (up to six) of CAN-3110 in arm C, reporting good tolerability and safety. In April 2024, we announced the

acceptance of an abstract at the ASCO Annual Meeting, to be presented in June 2024, that will feature data regarding the feasibility and tolerability of multiple injections of CAN-3110.

We are also designing other novel viral immunotherapy candidates using our proprietary enLIGHTEN™ Discovery Platform, a systematic, iterative HSV-based discovery platform leveraging human biology and advanced analytics to create new viral immunotherapy candidates for solid tumors. In October 2022, we entered into a collaboration with the University of Pennsylvania (UPenn) Center for Cellular Immunotherapies to study the impact of novel viral immunotherapy candidates based on Candel's enLIGHTEN™ Discovery Platform to strengthen the activity of UPenn's investigational CAR-T cell therapies in difficult to treat solid tumors. In November 2023, during the SITC 2023 Annual Meeting, we presented two posters describing the key elements of the platform and the development of the first experimental agent from the enLIGHTEN Discovery Platform. The new agent, Alpha-201 Macro1, is an investigational viral immunotherapy designed to interfere with the CD47/SIRPα pathway and activate innate immune surveillance. Results demonstrated monotherapy activity following local administration in a preclinical model of lung and breast cancer. Additional preclinical data presented at SITC confirmed the capability of the enLIGHTEN™ Advanced Analytics suite to predict optimal gene payload combinations to arm viral vectors, that enable the design of potential combination therapeutics to overcome tumor resistance especially in cancers resistant to ICI treatment.

In April 2024, during the American Association for Cancer Research's 2024 Annual Meeting, we presented data on a second pre-candidate from our enLIGHTEN™ Discovery Platform, a first-in-class multimodal immunotherapy for induction of tertiary lymphoid structures, being developed as a novel therapeutic strategy for solid tumors.

We currently own development and commercialization rights for our programs in major markets, including the United States, Europe and Asia, allowing us to control development and seek approval in those areas as we prepare our commercialization efforts.

We were incorporated in Delaware in June 2003 as Advantagene, Inc. (Advantagene). In December 2019, Advantagene licensed substantially all the assets of Periphagen, a company focused on engineering HSV as a gene therapy vector, and in September 2020, licensed CAN-3110 from Mass General Brigham (MGB). In December 2020, we formally changed our name from Advantagene to Candel Therapeutics, Inc. We completed our initial public offering in July 2021.

Our cash and cash equivalents were $25.7 million as of March 31, 2024. In accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC), 205-40, Presentation of Financial Statements - Going Concern, we are required to assess our ability to continue as a going concern for the one-year look forward period following the date that the condensed consolidated financial statements are issued. Based on our current operating plan and existing cash and cash equivalents, we determined that substantial doubt exists regarding our ability to continue as a going concern for the one-year period following the date these condensed consolidated financial statements are issued. To sustain its future operations beyond such one-year period, we will require additional funding. We expect to finance our cash needs through a combination of public or private equity or debt financings, government grants, and other sources, which may include collaborations, strategic alliances and licensing arrangements with third parties. There is no assurance that we will be successful in obtaining sufficient funding on acceptable terms, if at all, and could be forced to delay, reduce, or eliminate some or all of its research, clinical trials, product development or future commercialization efforts, which could materially adversely affect our business prospects or our ability to continue as a going concern.

The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the condensed consolidated financial statements have been prepared on a basis that assumes we will continue as a going concern and that contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Collaborations

We are a party to a number of license and collaboration agreements under which we license patents, patent applications and other intellectual property to and from third parties.

Periphagen. On December 9, 2019, we entered into a series of agreements, including an exclusive license agreement, a novation agreement, an equipment purchase agreement and an intellectual property assignment agreement, collectively the Periphagen Agreements, with Periphagen, whereby we acquired certain assets and licensed certain rights (including specified patent rights and know-how, or the Licensed IP Rights) of Periphagen, primarily consisting of exclusive rights to their technology platform and a portfolio of pre-clinical, development stage virus vectors. The primary classes of assets are HSV-derived assets expressing neurotrophin-3 (or NT-3 Assets) and other HSV-derived assets (Gene Transfer Neuro-Assets). Under the license agreement, Periphagen granted us a worldwide exclusive license with the right to grant sublicenses through multiple tiers under the Licensed IP Rights to conduct research and to develop, make, have made, use, have used, offer for sale, have sold, export and import products incorporating the Licensed IP Rights in all fields of use except the treatment, diagnosis, and prevention of nononcologic skin diseases and conditions (including use as an aesthetic).

On June 7, 2023, we entered into an amendment to the exclusive license agreement. Under the amendment, our rights to the NT-3 Assets and Gene Transfer Neuro-Assets reverted to Periphagen, and we no longer have any obligations (including without

limitation diligence obligations and payment obligations) with respect to the NT-3 Assets or Gene Transfer Neuro-Assets. With respect to the remaining Licensed IP Rights, we retained a worldwide exclusive license with the right to grant sublicenses through multiple tiers under the Licensed IP Rights to conduct research and to develop, make, have made, use, have used, offer for sale, have sold, export and import products incorporating the Licensed IP Rights in field of the treatment, diagnosis, and prevention of oncologic diseases and conditions.

Mass General Brigham (MGB). On January 20, 2018, we entered into an exclusive option agreement (the Option Agreement) with MGB. Pursuant to the Option Agreement, we obtained the exclusive right from MGB to negotiate a world-wide, royalty-bearing license to develop and commercialize products covered by certain MGB patents, including those patents covering CAN-3110, in the field of gene therapy and oncolytic vector therapy for the treatment or prevention of cancerous tumors in humans or animals, as such field is further detailed in the Option Agreement (the Licensed Field). In consideration for MGB's granting of the exclusive option, we paid MGB a non-refundable fee of $40,000.

Under the Option Agreement, we were required to use reasonable efforts to enter into a clinical trial agreement with MGB. We entered into such clinical trial agreement with MGB (MGB Clinical Trial Agreement) on June 19, 2018. Under the MGB Clinical Trial Agreement, we have committed to remitting financial support for the performance of a specified phase 1 clinical trial by MGB pursuant to a protocol summary contained in the Option Agreement.

On September 15, 2020, we exercised our option and entered into an exclusive patent license agreement with MGB (the MGB License Agreement). Under the MGB License Agreement, MGB granted to us (a) an exclusive, royalty-bearing license under certain of MGB's patents to make, have made, use, have used, sell and have sold certain products covered by such licensed patents (Licensed Products) and otherwise practice processes covered by such licensed patents (Licensed Processes); and (b) a non-exclusive, royalty-bearing license under certain other of MGB's patents to make, have made, use, have used, sell and have sold Licensed Products, but not to sell or have sold Licensed Processes. The foregoing rights are sublicensable, subject to sublicensing terms set forth in the MGB License Agreement. In connection with executing the MGB License Agreement, we paid a license issue fee and also agreed to reimburse MGB for all reasonable fees and expenses MGB had incurred and will incur for the preparation, filing, prosecution and maintenance of the licensed patent rights.

Ventagen. On March 1, 2014, we entered into an exclusive license agreement (the Ventagen Agreement) with Ventagen a related party. The Ventagen Agreement provides Ventagen an exclusive license, with rights to grant sublicense (subject to certain terms and conditions) under any worldwide patent rights and know-how owned or controlled by us during the term of the Ventagen Agreement which cover applicable technology utilizing the delivery method of the herpes derived TK protein to tumors or other tissues via a viral vector (as further specified therein), to research, use, have used, import, have imported, export, have exported, offer for sale, have sold, sell, distribute and market certain products for the prevention or treatment of cancer in humans and any use in animals (or the Field of Use), or the Licensed Products, for commercial sale and distribution within Mexico, Belize, Guatemala, Honduras, El Salvador, Costa Rica, Nicaragua, Panama, Colombia and Bolivia. Ventagen is 49.5% owned by certain of our stockholders.

Corporate Restructuring

In November 2023, our board of directors authorized a restructuring plan to focus on continuation and expansion of development of CAN-3110 as well as the enLIGHTEN™ Discovery Platform, which resulted in a reduction of our workforce by approximately 45%. Each affected employee's separation occurred in December 2023. As a result, we incurred costs of $0.7 million related to severance benefits for the affected employees, including severance payments and limited reimbursement of medical insurance premiums. The restructuring plan was completed in the first quarter of 2024 when the final severance payments of $46,000 were made.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from sales of products in the foreseeable future.

Operating Expenses

Our operating expenses since inception have consisted solely of research and development costs and general and administrative costs.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our product development activities for our two primary drug candidates, CAN-2409 and CAN-3110. We expense research and development costs as incurred. These include the following:

- employee-related costs, including salaries, benefits and stock-based compensation expense, for personnel engaged in research, development and clinical management functions;
- expenses incurred under agreements with third party clinical sites for the treatment and follow-up for patients enrolled in our clinical trials;
- the cost of acquiring and manufacturing preclinical study materials, including manufacturing registration and validation batches;
- payments made under third-party licensing agreements;
- costs incurred to develop the manufacturing process and capabilities for future clinical trials and commercialization. Our clinical trial material for use in our existing clinical trials was manufactured in prior years;
- costs related to compliance with quality and regulatory requirements;
- costs of outside consultants, primarily related to regulatory; and
- facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities and insurance, and other operating costs if specifically identifiable to research and development activities.

We expect that our research and development expenses will continue to increase substantially for the foreseeable future and will comprise a larger percentage of our total expenses as we complete our clinical trials and commence additional clinical trials, continue to discover and develop additional product candidates and develop and scale our manufacturing capabilities. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to increased scale and duration of later stage clinical trials.

We cannot determine with certainty the duration and costs of future clinical trials of CAN-2409 and CAN-3110 or any other product candidate we may develop or if, when, or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of, or obtain regulatory approval for, any of our current or future product candidates. The duration, costs, and timing of clinical trials and development of CAN-2409 and CAN-3110 and any other product candidate we may develop will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trials;
- our successful enrollment in and completion of clinical trials, including our ability to generate positive data from any such trials;
- our ability to add and retain key research and development personnel;
- the actual probability of success for our product candidates, including their safety and efficacy, early clinical data, competition, manufacturing capability, and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals;
- the progress of the development efforts of parties with whom we may enter into collaboration agreements, and the terms and timing of any additional collaboration agreements, license or other arrangement, including the timing of any payments thereunder;
- our ability to enter into agreements with contract development and manufacturing organizations (CDMOs) for the development, clinical manufacture and commercial manufacture of our product candidates CAN-2409 and CAN-3110;
- costs related to manufacturing of our product candidates or to account for any future changes in our manufacturing plans;
- our ability to successfully commercialize our product candidates, if and when approved;
- raising additional funds necessary to complete clinical development of our product candidates;

- our ability to obtain and maintain third-party insurance coverage and adequate reimbursement for our product candidates, if and when approved;
- the acceptance of our product candidates, if approved, by patients, the medical community and third-party payors;
- effectively competing with other products if our product candidates are approved;
- the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers, or other vendors resulting from any future public health crisis or ongoing geopolitical conflicts and related global economic sanctions;
- our ability to maintain a continued acceptable safety profile for our therapies following approval;
- our ability to obtain and maintain patents, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates, both in the United States and internationally; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, business development, and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs including directors and officers insurance; travel expenses; and facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities, and other operating costs that are not specifically attributable to research and development activities.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support our continued clinical development and manufacturing activities and to meet the requirements of a public company. We expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission (SEC) requirements; director and officer insurance costs; and investor and public relations costs.

Grant Income

Grant income consists of amounts received under a grant from the Massachusetts Life Sciences Center.

Interest Income

Interest income consists of amounts earned on investment of cash equivalents.

Interest Expense

Interest expense consists of interest expense on our debt under our Loan Agreement with Silicon Valley Bank (SVB).

Change in Fair Value of Warrant Liability

In connection with the November 13, 2018 issuance of Series B preferred stock we issued warrants to the purchasers of the Series B preferred stock, to purchase up to 7,344,968 shares of our common stock with an exercise price of $6.81 per share. We also issued a warrant to the NC Incorporated Ohio Trust, an irrevocable trust funded by us, to purchase 162,740 shares of our common stock, $0.01 par value, at an exercise price of $1.46 per share, subject to adjustments as specified in the warrant agreement (the NC Ohio Warrants). Certain of those warrants are recorded as a liability on our balance sheet. The warrants recorded as a liability are remeasured to their fair value at each reporting date with changes in the fair value recognized as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. We will continue to recognize changes in the fair value of the warrants until they are exercised, expire or qualify for equity classification. The fair value of the warrants is determined based on significant inputs not observable in the market. The fair value of the warrants uses various valuation methods, including the Monte Carlo method, the option-pricing method, probability-weighted expected return and the hybrid method, all of which incorporate assumptions and estimates, to value the common stock warrants. The hybrid method is often used when a company is expecting a liquidity event in the near future and is a combination of the option-pricing and probability-weighted expected return methods. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying shares of common stock, risk-free interest rate, expected dividend yield, and the remaining contractual term of the warrants. Therefore, the fair value may not be appropriately captured by simple models.

Income Taxes

Since our inception, we have generated cumulative federal and state net operating loss and research and development credit carryforwards for which we have not recorded any net tax benefit due to uncertainty around utilizing these tax attributes within their respective carryforward periods.

As of December 31, 2023, we had federal net operating loss carryforwards (NOLs) of approximately $86.2 million and state NOLs of approximately $79.6 million which may be available to offset future taxable income. Our federal NOLs include $8.8 million available to reduce future taxable income through 2037 and approximately $77.4 million of NOLs that do not expire and are available to reduce future taxable income indefinitely. The state NOLs are available to offset future taxable income through 2033. As of December 31, 2023, we also had federal and state research and development tax credit carryforwards of $4.5 million and $2.2 million, respectively, which are available to offset federal and state tax liabilities through 2043 and 2038, respectively.

Realization of future tax benefits is dependent on many factors, including our ability to generate taxable income within the NOL period. Our management has evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets, which are comprised principally of net operating loss carryforwards and certain tax credits. Management has considered our history of cumulative net losses incurred since inception, as well as our lack of product revenue since inception, and has determined that it is more likely than not that we will not realize the benefits of its deferred tax assets. As a result, a full valuation allowance has been established at March 31, 2024 and December 31, 2023.

NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as provided under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), as well as under similar state provisions. These ownership changes may limit the amount of NOLs that can be utilized annually to offset future taxable income. In general, an ownership change, as defined under Section 382 of the Code (Section 382), results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. We have completed several financings and not yet determined if such a limitation would be placed against our NOL. We will make such a determination prior to the utilization of any NOL.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

The following table summarizes our results of operations for the three months ended March 31, 2024 and 2023 (in thousands):

	THREE MONTHS ENDED MARCH 31,		
	2024	2023	CHANGE
Operating expenses:			
Research and development	$ 4,102	$ 5,469	$ (1,367)
General and administrative	3,800	4,164	(364)
Total operating expenses	7,902	9,633	(1,731)
Loss from operations	(7,902)	(9,633)	1,731
Grant income	—	12	(12)
Interest income	320	711	(391)
Interest expense	(646)	(609)	(37)
Change in fair value of warrant liability	7	724	(717)
Net loss	$ (8,221)	$ (8,795)	$ 574

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2024 and 2023 (in thousands):

	THREE MONTHS ENDED MARCH 31,		INCREASE
	2024	2023	(DECREASE)
Employee-related	$ 2,728	$ 3,425	$ (697)
Clinical development	826	1,361	(535)
Depreciation of fixed assets	248	227	21
Occupancy	129	140	(11)
Pre-clinical research	52	92	(40)
Recruiting	—	93	(93)
Other	119	131	(12)
	$ 4,102	$ 5,469	$ (1,367)

Research and development expenses decreased $1.4 million from $5.5 million for the three months ended March 31, 2023 to $4.1 million for the three months ended March 31, 2024. The decrease was primarily attributable to a $0.7 million decrease in employee-related expenses due to the corporate restructuring in the fourth quarter of 2023 and a $0.5 million decrease in clinical development costs driven by decreased regulatory costs for CAN-2409 programs.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2024 and 2023 (in thousands):

	THREE MONTHS ENDED MARCH 31,		INCREASE
	2024	2023	(DECREASE)
Professional and consulting fees	$ 1,668	$ 1,166	$ 502
Employee-related	1,639	2,254	(615)
Insurance	321	449	(128)
Occupancy	45	41	4
Recruiting	—	43	(43)
Other	127	211	(84)
	$ 3,800	$ 4,164	$ (364)

General and administrative expenses decreased $0.4 million from $4.2 million for the three months ended March 31, 2023 to $3.8 million for the three months ended March 31, 2024. The decrease was primarily attributable to a $0.6 million decrease in employee-related expenses due to the corporate restructuring in the fourth quarter of 2023 and a $0.1 million decrease in the cost of directors and officers insurance. These decreases were partially offset by a $0.5 million increase in professional and consulting fees.

Grant Income

Grant income was zero and $12,000 for the three months ended March 31, 2024 and 2023, respectively. Grant income for the three months ended March 31, 2023 relates to the recognition of income from a grant from the Massachusetts Life Sciences Center.

Interest Income

Interest income was $0.3 million for the three months ended March 31, 2024, compared to interest income of $0.7 million for the three months ended March 31, 2023, and represents earnings on our cash equivalents. The decrease in interest income is the result of interest being generated on a lower cash equivalents balance for the three months ended March 31, 2024 compared to the three months ended March 31, 2023.

Interest Expense

Interest expense was $0.6 million for each of the three months ended March 31, 2024 and 2023, and represents interest expense on our outstanding debt obligations.

Change in Fair Value of Warrant Liability

The change in fair value of our warrant liability was a decrease of $7,000 for the three months ended March 31, 2024, compared to a decrease of $0.7 million for the three months ended March 31, 2023. The change in fair value of the warrant liability is primarily driven by changes in the underlying value of our stock price.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our product candidates. We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials for our product candidates, developing our manufacturing capabilities which may include the cost of establishing a relationship with contract manufacturers to support commercial launch of our product candidate CAN-2409 and costs associated with equipping our laboratory and manufacturing facility to support clinical trials and commercialization and providing general and administrative support for our operations, including the cost associated with operating as a public company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources. Based on current plans and assumptions, we expect that our existing cash and cash equivalents will be sufficient to fund our current operating plan into the fourth quarter of 2024.

We do not currently have any approved products and have never generated any revenue from product sales. We have financed our operations primarily through proceeds from government grants and proceeds from the sale of convertible notes, common stock, and our convertible preferred stock. As of March 31, 2024, we have raised approximately $161.2 million, including $15.6 million of government grants, $66.1 million from the sale of convertible preferred stock, and $79.5 million from the sale of our common stock. Our cash and cash equivalents totaled $25.7 million as of March 31, 2024. We had $19.7 million of debt as of March 31, 2024. As of March 31, 2024, we have raised $0.2 million under our ATM Program (as defined below). We did not raise any additional funds under our ATM Program subsequent to March 31, 2024.

On February 24, 2022, we entered into a loan and security agreement Loan Agreement with SVB pursuant to which SVB agreed to provide term loans to us in an aggregate principal amount of $20.0 million. We borrowed $20.0 million upon entering into the Loan Agreement. We could have borrowed up to an additional aggregate principal amount not to exceed $5.0 million, at any time on or prior to December 31, 2022, upon the achievement of all of the following milestones, inclusively: (a) positive phase 2 clinical activity data from our CAN-2409 NSCLC clinical trial, (b) dosing of our first patient in our phase 3 CAN-2409 high-grade glioma clinical trial; and (c) receipt on or prior to December 31, 2022, of net cash proceeds in an amount equal to at least $75.0 million from the issuance and sale of equity securities to investors acceptable to SVB. We did not borrow any of the additional aggregate principal amount on or prior to December 31, 2022. The term loans are secured by substantially all of our properties, rights and assets, except for our intellectual property, which is subject to a negative pledge under the Loan Agreement.

The term loans bear interest at a floating rate per annum equal to the greater of (A) 5.75% and (B) the prime rate (as published in the money rates section of The Wall Street Journal) plus 2.50%. We are required to make monthly interest payments, and commencing on February 1, 2024, 24 consecutive installments of principal plus monthly payments of accrued interest. The term loans mature on January 1, 2026. Upon repayment in full of the term loans, we will be required to pay a final payment fee equal to 4.50% of the original principal amount of any funded term loan being repaid. The Loan Agreement permits voluntary prepayment of all, but not less than all, of the SVB term loans, subject to a prepayment premium of 1% to 3% based upon the timing of the prepayment.

On August 5, 2022, we filed a shelf registration statement on Form S-3 (as amended, the Shelf) with the SEC, which covers the offering, issuance and sale by us of up to an aggregate of $200.0 million of our common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. We simultaneously entered into a sales agreement with Jefferies LLC, as sales agent, to provide for the issuance and sale by us of up to $75.0 million of our common stock from time to time in “at-the-market” offerings under the Shelf (the ATM Program). The Shelf was declared effective by the SEC on August 12, 2022. As of May 6, 2024, we have sold and issued 109,485 shares of common stock under the ATM Program, with total net proceeds of $0.2 million.

As of March 31, 2024, we had an accumulated deficit of $145.2 million and have not generated any product sales. We do not know when, or if, we will generate revenue from product sales. We will not generate significant revenue from product sales unless and until we obtain regulatory approval and commercialize one of our current or future product candidates. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical and contract manufacturing costs, legal and other regulatory expenses, and general overhead costs. We expect that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to risks in the development of our products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We will require substantial additional financing to fund our operations and to continue to execute our strategy, and we will pursue a range of options to secure additional capital.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise capital when needed or on acceptable terms, it would have a negative impact on our financial condition and we could be forced to delay, reduce or eliminate our research, clinical trials, product development or future commercialization efforts.

Cash Flows

The following table summarizes our sources and uses of cash for the periods presented (in thousands):

	THREE MONTHS ENDED MARCH 31,	
	2024	2023
Net cash used in operating activities	$ (8,438)	$ (10,819)
Net cash (used in) provided by investing activities	(7)	19
Net cash used in financing activities	(1,255)	—
Net decrease in cash and cash equivalents	$ (9,700)	$ (10,800)

Cash Flows for the three months ended March 31, 2024 and 2023

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2024 was $8.4 million, primarily consisting of a net loss of $8.2 million as we incurred expenses associated with our clinical programs and incurred costs associated with operating as a public company. We had non-cash charges of $1.5 million in non-cash charges primarily related to non-cash stock compensation and depreciation expense. Net cash used in operating activities was also impacted by $1.7 million in changes in operating assets and liabilities, primarily driven by a decrease of $1.6 million in accrued expenses.

Net cash used in operating activities for the three months ended March 31, 2023 was $10.8 million, primarily consisting of a net loss of $8.8 million as we incurred expenses associated with our clinical programs, increased our headcount and incurred costs associated with operating as a public company. In addition, we had non-cash income of $0.7 million as a result of the change in the fair value of our warrant liability. Non-cash income was partially offset by $1.2 million in non-cash charges primarily related to non-cash stock compensation and depreciation expense. Net cash used in operating activities was also impacted by $2.5 million in changes in operating assets and liabilities, primarily driven by a decrease of $1.8 million in accrued expenses and a $0.7 million increase to prepaid expenses and other current assets.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2024 was $7,000 and consisted of the purchase of fixed assets.

Net cash provided by investing activities for the three months ended March 31, 2023 was $19,000 and consisted of proceeds from the sale of fixed assets, which was partially offset by the purchase of fixed assets.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2024 was $1.3 million and consisted of $1.7 million of principal payments on our term loan with SVB, partially offset by $0.2 million of proceeds from option exercises and $0.2 million of net proceeds from the issuance of common stock under our ATM Program.

There were no financing activities for the three months ended March 31, 2023.

Funding Requirements

We expect our operating expenses to increase substantially in the future in connection with our ongoing activities, particularly as we advance CAN-2409 and CAN-3110 through research and development, clinical trials, and develop our manufacturing capabilities, as we research and develop additional product candidates including preclinical activities and as we prepare for marketing approval and commercialization. We also expect to incur additional costs associated with operating as a public company.

Specifically, our costs and expenses will increase as we:

- advance the clinical development of CAN-2409 and CAN-3110;

•develop our manufacturing capabilities, including through relationships with contract manufacturers for commercial manufacturing of our product candidate CAN-2409 and the development, construction and qualification of our clinical manufacturing capabilities, internally or through CDMOs for our product candidate CAN-3110;

•pursue the preclinical and clinical development of other product candidates using our enLIGHTEN™ Discovery Platform, an HSV-based platform; and

•expand our operational, financial, and management systems and increase personnel, including personnel to support our operations as a public company.

We believe that our existing cash and cash equivalents as of March 31, 2024, will enable us to fund our operating expenses and capital expense requirements into the fourth quarter of 2024. We have based this estimate on assumptions that may prove to be incorrect, and we could utilize our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with the research, development, and commercialization of therapeutics, it is difficult to estimate with certainty the amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

•the progress, costs, and results of our clinical development and clinical trials for CAN-2409 and CAN-3110;

•the progress, costs, and results of our additional research and preclinical development programs;

•the costs, timing and outcome of regulatory review of our product candidates;

•our ability to establish and maintain collaborations on favorable terms, if at all;

•the outcome, timing and cost of meeting regulatory requirements established by the FDA and comparable foreign regulatory authorities, if applicable, for our product candidates;

•the costs and timing of internal and external process development for our manufacturing capabilities;

•the scope, progress, results, and costs of any product candidates that we may derive from our HSV-based platform or with collaborators;

•the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; hire additional personnel in research, manufacturing, and regulatory and clinical development, as well as management personnel;

•the extent to which we in-license or acquire rights to other products, product candidates, or technologies;

•additions or departures of key scientific or management personnel;

•the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution for any of our product candidates for which we obtain marketing approval;

•the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and

•the costs of operating as a public company.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our cash needs through a combination of public or private equity or debt financings and other sources, which may include collaborations strategic alliances and licensing arrangements with third parties. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. Debt financing and equity financing, if available, may involve agreements that include restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business, in addition to those restrictive covenants contained in the Loan Agreement. If we raise additional funds through other sources, such as collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, product development, and research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

Our primary contractual obligations are our facility lease, the Loan Agreement with SVB, and the Periphagen Note. The table below summarizes the contractual obligations that will become due as of March 31, 2024 (in thousands):

		PAYMENTS DUE BY PERIOD (in thousands)		
	TOTAL	LESS THAN 1 YEAR	1 TO 3 YEARS	3 TO 5 YEARS
Operating lease obligation [1]	$ 1,478	$ 602	$ 876	$ —
Loan Agreement with SVB [2]	21,199	11,537	9,662	—
Periphagen Note [3]	1,352	—	—	1,352
Total	$ 24,029	$ 12,139	$ 10,538	$ 1,352

[1] Represents future minimum lease payments under our operating lease for office and laboratory space at our Needham, Massachusetts facility. Our facility lease extends to August of 2026.

[2] Represents future principal, interest payments, and the final payment fee on our Loan Agreement with SVB, which matures on January 1, 2026.

[3] Represents a $1.0 million promissory note plus interest under the terms of our asset purchase agreements with Periphagen, Inc. The promissory note is due upon maturity in November 2027.

See our condensed consolidated financial statements and related footnotes elsewhere in this Form 10-Q for additional information on these agreements.

We also enter into contracts in the normal course of business with hospitals, clinics, universities, and other third parties for clinical trials and testing and with construction contractors and process developers for the construction of our manufacturing facility. These contracts do not contain minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancelation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancelation. These payments are not included in the table above as the amount and timing of such payments are not known.

Critical Accounting Estimates

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

During the three months ended March 31, 2024, there were no material changes to our critical accounting estimates as reported in our Annual Report on Form 10-K for the year ended December 31, 2023. For a full discussion of these estimates, see "*Critical Accounting Estimates*" within "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" in our Annual Report on Form 10-K for the year ended December 31, 2023.

Recent Accounting Pronouncements

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations, or cash flows is disclosed in Note 2 to our condensed consolidated financial statements included elsewhere in this Form 10-Q.

Emerging Growth Company Status

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the JOBS Act) was enacted. Section 107 of the JOBS Act provides that an "emerging growth company," or an EGC, can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (the Securities Act) for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of

equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information under this item.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities and Exchange Act of 1934, as amended). We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our Chief Executive Officer and Interim Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2024. Based on the evaluation of our disclosure controls and procedures as of March 31, 2024, our Chief Executive Officer and Interim Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is 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.

We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

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

Risks Related to Our Business, Financial Position and Capital Requirements

We are a biopharmaceutical company with a limited operating history and have not generated any revenue to date from product sales.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We were incorporated under the laws of the State of Delaware in June 2003. Since inception, we have focused substantially all of our efforts and financial resources on raising capital and developing our initial product candidates. To date, we have financed our operations primarily through the issuance and sale of our convertible preferred stock to outside investors in private equity financings and from the proceeds of the sale of our common stock. From our inception through March 31, 2024, we raised an aggregate of $145.6 million of gross proceeds from such transactions. In addition, in February 2022, we borrowed $20.0 million under the Loan Agreement with SVB. As of March 31, 2024, our cash and cash equivalents were $25.7 million. We have incurred net losses in each year since our inception, and we had an accumulated deficit of $145.2 million as of March 31, 2024. For the three months ended March 31, 2024 and 2023, we reported net losses of $8.2 million and $8.8 million, respectively. We have no products approved for commercial sale and therefore have never generated any revenue from product sales, and we do not expect to do so in the foreseeable future. We have not obtained regulatory approvals for any of our product candidates, and even if our clinical development efforts result in positive data, our product candidates may not receive regulatory approval or be successfully introduced and marketed at prices that would permit us to operate profitably.

We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect our research and development expenses to significantly increase in connection with the commencement and continuation of clinical trials of our product candidates. In addition, if we obtain marketing approval for our product candidates, we will incur significant sales, marketing and manufacturing expenses. We are incurring additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

The amount of our future losses is uncertain, and our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

- Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

•the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;

•our ability to successfully enroll and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;

•our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;

•the changing and volatile U.S. and global economic environments, including as a result of any future public health crisis;

•the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;

•the cost of manufacturing our product candidates, which may vary depending on the quantity of production, and the success of achieving clinical-scale manufacturing operations in our new facility or through CDMOs and commercial manufacturing at third-party manufacturers;

•our ability to attract, hire and retain qualified personnel;

•expenditures that we will or may incur to develop additional product candidates;

•the level of demand for our product candidates should they receive approval, which may vary significantly;

•the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates; and

•future accounting pronouncements or changes in our accounting policies.

The cumulative effects 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. 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.

We have no products approved for commercial sale and have not generated any revenue from product sales.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our product candidates, and we do not expect to generate any revenue from the sale of products in the near future. We do not expect to generate significant revenue unless and until we obtain marketing approval of, and begin to sell, one or more of our product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

•successfully complete our ongoing and planned preclinical studies and clinical trials for our viral immunotherapy programs;

•timely file and receive clearance of our Investigational New Drug applications (INDs), in order to commence our planned clinical trials or future clinical trials;

•successfully enroll subjects in, and complete, clinical trials for our viral immunotherapy programs;

•timely file marketing applications and receive regulatory approvals for our product candidates from the FDA and comparable foreign regulatory authorities;

•initiate and successfully complete all safety studies required to obtain U.S. and foreign marketing approval for our product candidates;

•establish clinical supply capabilities through arrangements with third-party manufacturers for clinical supply and commercial manufacturing;

•obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;

•launch commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;

•maintain a continued acceptable safety profile of the product candidates following approval;

•obtain and maintain acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;

•position our products to effectively compete with other therapies;

•obtain and maintain favorable coverage and adequate reimbursement by third-party payors for our product candidates;

•enforce and defend intellectual property rights and claims with respect to our product candidates; and

•hire additional staff, including clinical, scientific and management personnel.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

There is substantial doubt regarding our ability to continue as a going concern. We will need to raise substantial additional funding, which may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate some of our product development programs or commercialization efforts.

The development of pharmaceutical products is capital-intensive. We are currently advancing our product candidates through clinical development across a number of potential indications. We expect our expenses to significantly increase in connection with our ongoing activities, particularly as we continue our ongoing clinical trials or initiate future trials and pursue the research and development of, and seek marketing approval for, our product candidates. In addition, depending on the status of regulatory approval or, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our product candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, we incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate certain of our research and development programs or future commercialization efforts, and may be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

We expect that our existing cash and cash equivalents will be sufficient to fund our current operating plan into the fourth quarter of 2024. However, our future capital requirements will depend on and could increase significantly as a result of many factors, including:

•the scope, progress, results and costs of product discovery, preclinical and clinical development, laboratory testing, manufacturing and clinical trials for the development of CAN-2409, CAN-3110, or our other potential product candidates;

•the timing of, and the costs involved in, obtaining marketing approvals for CAN-2409 in newly diagnosed localized prostate cancer, NSCLC, and borderline resectable pancreatic cancer as well as for CAN-3110 in our initial target indication of recurrent HGG and our other potential product candidates that we may develop;

•if approved, the costs of commercialization activities for CAN-2409 or CAN-3110 for any approved indications or any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of a collaborator that we may contract with in the future, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;

•the scope, prioritization and number of our research and development programs;

•the costs, timing and outcome of regulatory review of our product candidates;

•our ability to establish and maintain additional collaborations on favorable terms, if at all;

•the achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we may enter into;

•the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;

•the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

•the extent to which we acquire or in-license other product candidates and technologies;

- the costs of securing manufacturing arrangements for commercial production;
- the emergence of competing viral immunotherapies as well as immuno-oncology therapies in general and other adverse market developments;
- the costs of establishing clinical manufacturing operations through CDMOs;
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates; and
- the impact of any future public health crisis, which may exacerbate the magnitude of the factors discussed above.

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

As of March 31, 2024, our cash and cash equivalents were $25.7 million. Based on our current business plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the quarter ended March 31, 2024 are issued and we need to raise significant amounts of additional funding to complete all of our ongoing trials and execute on our business plan. Financing may not be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. In addition, our efforts to raise additional capital may divert our management from their day-to-day activities, which may adversely affect our ability to develop our product candidates in a timely manner.

The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain adequate funding on a timely basis, we may be required to revise our business plan and strategy and potentially curtail, delay, or discontinue one or more of our clinical trials, our research efforts, product development, future commercialization efforts, or may result in our being unable to expand our operations or otherwise capitalize on our business opportunities. As a result, our business, financial condition and results of operations could be materially affected.

Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In November 2023, we undertook an organizational restructuring that significantly reduced our workforce. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of our remaining employees. Our restructuring may lead to employee litigation related to the headcount reduction, which could be costly and prevent management from fully concentrating on the business.

Any future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, and loss of employees and reduced productivity among remaining employees. For example, the workforce reduction may negatively impact our clinical, regulatory, technical operations, and commercial functions, should we choose to continue to pursue them, which would have a negative impact on our ability to successfully develop, and ultimately, commercialize our product candidates. Our future financial performance and our ability to develop our product candidates or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be.

We have incurred indebtedness, and we may incur additional indebtedness, which could adversely affect our financial condition.

On February 24, 2022, we entered into a loan and security agreement (the Loan Agreement) with Silicon Valley Bank, as lender (SVB), pursuant to which SVB has agreed to provide term loans to us in an aggregate principal amount of up to $25.0 million. Our indebtedness could have important consequences to our stockholders. For example, it:

- increases our vulnerability to adverse general economic and industry conditions;
- limits our flexibility in planning for, or reacting to, changes in our business or the industries in which we operate by restricting our ability to make acquisitions, investments or divestments, or take other corporate actions quickly; and
- limits our ability to obtain additional financing or refinancing in the future for working capital, clinical trials, research and development, or other purposes.

Any of the above-listed factors could materially adversely affect our business, financial condition, results of operations, and cash flows. The Loan Agreement also contains certain covenants, including limitations on, among other things, additional indebtedness, making certain dispositions, paying dividends in certain circumstances, and making certain acquisitions and investments. Any failure to comply with the terms, covenants and conditions of the Loan Agreement may limit our ability to draw upon additional tranches of term loans and may result in an event of default under such agreement entitling the lender to accelerate our indebtedness, which could have a material adverse effect on our business, financial condition, and results of operations.

Recent increases in interest rates have increased our borrowing costs and may also affect our ability to obtain working capital through borrowings such as bank credit lines and public or private sales of debt securities, which may result in lower liquidity, reduced working capital and other adverse impacts on our business.

A portion of our outstanding debt under the Loan Agreement, bears interest at variable interest rates. To meet our liquidity needs, we have relied in part on borrowed funds with variable interest rates and may continue to do so in the future. Continued increase in interest rates may increase the cost of new indebtedness and the servicing of our outstanding indebtedness, and could materially and adversely affect our results of operations, financial condition, liquidity and cash flows.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. We currently have a $20 million loan outstanding pursuant to a $25 million term loan facility with SVB, which was entered into in February 2022 and amended in June 2023. We no longer have access to borrow the $5 million of additional aggregate principle per the terms of the Loan Agreement. In addition, if any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, such as us, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB, and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have credit

agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to, or reductions in borrowings available under revolving existing credit facilities or other working capital sources and/or delays, inability or reductions in our ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements;
- Potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- Potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our customers or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer or supplier bankruptcy or insolvency, or the failure of any customer to make payments when due, or any breach or default by a customer or supplier, or the loss of any significant supplier relationships, could result in material losses to us and may have a material adverse impact on our business.

Risks Related to Product Development

Our business is dependent on the success of our most advanced product candidate, CAN-2409, as well as CAN-3110 and any other product candidates that we advance into the clinic. All of our product candidates will require additional development before we may be able to seek regulatory approval for and launch a product commercially.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to our CAN-2409 program, which is currently our most advanced product candidate.

If CAN-2409, CAN-3110 or any other product candidate we develop encounters safety or efficacy issues, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed. We can provide no assurance that CAN-2409, CAN-3110 or any other product candidates we develop will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. If we were required to discontinue development of CAN-2409, CAN-3110 or any future product candidate, or if CAN-2409, CAN-3110, or any future product candidate do not receive regulatory approval or fail to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever.

Furthermore, even if we obtain regulatory approval for CAN-2409, CAN-3110 or any other product candidates we develop, we will still need to develop a commercial infrastructure, expand our manufacturing capabilities or develop relationships with collaborators to commercialize, establish a commercially viable pricing structure and obtain coverage and adequate reimbursement from third-party payors, including government healthcare programs. If we, or any future collaborators, are unable to successfully commercialize CAN-2409, CAN-3110 or any other product candidates we develop, we may not be able to generate sufficient revenue to continue our business.

Our preclinical studies and clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval, and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, including CAN-2409, CAN-3110 or any other product candidates we develop, we must demonstrate the safety and efficacy of our product candidates for use in each target indication through lengthy, complex, and expensive preclinical studies and clinical trials. Failure can occur at any time during the preclinical study and clinical trial processes and there is a high risk of failure, so we may never succeed in developing marketable products. Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety and efficacy necessary to obtain regulatory approval to market any of our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety or 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. While we are currently in a phase 3 clinical trial for CAN-2409 for prostate cancer and are in early stages of clinical development for CAN-3110, it is likely, as is the case with many oncology therapies, that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Our product candidates have caused side effects in clinical trials related to on-target toxicity such as fever, chills and muscle aches and other flu-like symptoms. The most common side effects observed in our clinical trials have been transient, injection site-related reactions, and flu-like symptoms. The specific symptoms are largely dependent on the tumor site (site of injection). Patients who have participated in our trials have experienced grade 3 and grade 4 treatment-related side effects, including blood abnormalities. Those include pyrexia, genitourinary toxicity, increased aspartate transaminase / alanine transaminase (AST/ALT), increased bilirubin, hemiparesis or worsening of speech impairment (in studies of HGG), insomnia, headache, wound complications, empyema, motor-neuropathy symptoms/signs, transient lymphopenia, dehydration with renal insufficiency, urinary retention, worsening abdominal pain and increased lipase. Different nomenclature for the same side effect can be used in different trials (i.e. lymphopenia or low lymphocyte count). If on-target toxicity is observed at unacceptable levels, or if our product candidates have characteristics that are unexpected, we may need to 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. In addition, our product candidates could cause undesirable side effects that we have not observed yet to date. 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. In addition to our ongoing clinical trials of CAN-2409 and CAN-3110, patients have been, and may continue to be, treated with CAN-2409 and/or CAN-3110 under an expanded access or “compassionate use” program. To the extent the experiences of patients being treated in this program are inconsistent with or less favorable than the results of our ongoing or planned company-sponsored trials with CAN-2409 and/or CAN-3110, it may negatively affect perceptions of CAN-2409 and/or CAN-3110, our other product candidates, or our business. In addition, the FDA or comparable foreign regulatory authorities may require us to obtain and submit additional clinical data due to these inconsistent or unfavorable results, which could delay clinical development or marketing approval of CAN-2409 and/or CAN-3110 or potentially our other product candidates.

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

From time to time, we may publish interim, topline or preliminary data from our clinical trials. We may decide to conduct an interim analysis of the data after a certain number or percentage of patients have been enrolled, or after only a part of the full follow-up period but before completion of the trial. Similarly, we may report topline or preliminary results of primary and key secondary endpoints before the final trial results are completed. Preliminary, topline and interim data from our clinical trials may change as more patient data or analyses become available. Preliminary, topline or interim data from our clinical trials are not necessarily predictive of final results and are subject to the risk that one or more of the clinical outcomes may materially change

as patient enrollment continues, more patient data become available and we issue our final clinical trial report. These 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, preliminary, interim and topline data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from more complete results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain marketing authorization for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may not be successful in our efforts to identify additional product candidates or indications. Due to our limited resources and access to capital, we must prioritize development of certain product candidates and indications; these decisions may prove to be wrong and may adversely affect our business.

Although we intend to explore other therapeutic opportunities, in addition to the product candidates and indications that we are currently developing, we may fail to identify successful product candidates or additional indications for clinical development for a number of reasons. If we fail to identify additional potential product candidates or indications for development, our business could be materially harmed.

Research programs to pursue the development of our planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources than we possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. For example, at the Annual Meeting of SITC in Boston in November 2022, due to promising clinical activity of CAN-3110 in recurrent HGG, we made a portfolio and resource decision to prioritize CAN-3110 in recurrent HGG and not to pursue a phase 3 clinical trial of CAN-2409 in HGG.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

Results of earlier studies and trials of our product candidates may not be predictive of future trial results.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. As we commence new clinical trials and continue our ongoing clinical trials, issues may arise that could suspend or terminate such clinical trials. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies, including our oncology mouse studies and other animal studies, may not be predictive of the results of outcomes in human clinical trials. For example, our oncology product candidates

that are in preclinical development may demonstrate different chemical and biological properties in patients than they do in laboratory animal studies or may interact with human biological systems in unforeseen or harmful ways.

Additionally, some of past, ongoing and planned clinical trials utilize an “open-label” study design including our NSCLC trial in combination with ICI. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect, as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have improved notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trials when studied in a controlled environment with a placebo or active control.

Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval, if at all.

We have concentrated our research and development efforts on our CAN-2409 and CAN-3110 product candidates, and our future success largely depends on the successful development of these therapeutic approaches. In particular, CAN-2409 utilizes an adenovirus to activate the innate and adaptive immune system. To our knowledge, there are no FDA-approved products for the treatment of cancer that utilize the adenovirus.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. Few viral immunotherapies have been approved globally or by the FDA to date. While the first oncolytic viral immunotherapy, talimogene laherparepvec (Imlygic, Amgen), has received FDA approval, regulatory agencies have reviewed relatively few viral immunotherapy product candidates such as CAN-2409 and CAN-3110. This may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. Further, any viral immunotherapies that are approved may be subject to extensive post-approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to compliance with these requirements.

The FDA may also require a panel of experts, referred to as an advisory committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the advisory committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the advisory committee’s recommendations. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

In addition, our product candidates are live, gene-modified viruses for which the FDA, the European Medicines Agency (EMA) and other comparable foreign regulatory authorities and other public health authorities, such as the Centers of Disease Control and Prevention and hospitals involved in clinical studies, have established additional safety and contagion rules and procedures, which could establish additional hurdles for the development, manufacture or use of our vectors. These hurdles may lead to delays in the conduct of clinical trials or in obtaining regulatory approvals for further development, manufacturing or commercialization of our product candidates. We may also experience delays in transferring our process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

Furthermore, there has been limited historical clinical trial experience for the development of products that utilize the adenovirus. Moreover, the design and conduct of our clinical trials differs from the design and conduct of previously conducted clinical trials in this area. In particular, regulatory authorities in the United States and in other jurisdictions, including Europe, have not issued definitive guidance as to how to measure and demonstrate efficacy in newly diagnosed localized prostate cancer in intermediate- to high-risk patients in combination with the standard of care (SoC). As a result, there is substantial risk that the design or outcomes of our clinical trials will not be satisfactory to support marketing approval. For example, the endpoint in our phase 3 clinical trial investigating CAN-2409 in prostate cancer is a disease-free survival (DFS) endpoint with final results expected 24 months after last patient treated, which has not been utilized in prior trials and may not be accepted by regulators as a basis for approval despite the existence of the SPA. Even if this type of novel endpoint is accepted as a basis for approval in the United States, we cannot be certain that regulators outside of the United States will accept such endpoints or will not require us to conduct additional validation studies to support the suitability of such endpoints for approval in these jurisdictions.

We are developing, and in the future may develop, other product candidates, in combination with other therapies, which exposes us to additional risks related to any prodrugs or any agents used in combination with our product candidates.

Our CAN-2409 product candidate is being developed to be used in combination with the prodrug valacyclovir, which is an oral small molecule drug marketed for treatment of herpes infections. In the future, we may develop other product candidates to be used with one or more currently approved other therapies. Even if any product candidate we develop 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 or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

If the FDA or comparable foreign regulatory authorities revoke their approval of these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval.

We may also evaluate our future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delays in their clinical trials and lack of FDA approval.

Negative developments in the field of immuno-oncology and, in particular, viral immunotherapy, could damage public perception of any of our product candidates and negatively affect our business.

The commercial success of adenovirus- or HSV-based product candidates will depend in part on public acceptance of the use of immuno-oncology, and, in particular, viral immunotherapy. Adverse events in clinical trials of CAN-2409, CAN-3110 or any other adenovirus- or HSV-based product candidates which we may develop, or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for any adenovirus- or HSV-based product candidates that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of viral immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. In addition, responses by national or state governments to negative public perception may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, prospects and results of operations and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. As a result, we may not be able to continue or may be delayed in conducting our development programs.

Our product candidates consist of modified viruses. Adverse developments in clinical trials of other immunotherapy products based on viruses, like oncolytic viruses, may result in a disproportionately negative effect for our technologies as compared to other products in the field of infectious disease and immuno-oncology that are not based on viruses. Future negative developments in the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our product candidates.

Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates, and ultimately delay or prevent regulatory approval.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of completion of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. 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 as required by the FDA or comparable foreign regulatory authorities, or as needed to provide appropriate statistical power for a given trial. In particular, because we are focused on patients with brain cancer for the development of CAN-3110, our ability to enroll eligible patients may be limited or enrollment may be slower than we anticipate due to the small eligible patient population. In addition, our ability to enroll patients may be delayed by any future public health crisis and we are unable to predict the full extent and scope of such delays.

In addition to the potentially small target populations for our planned clinical trials, particularly in brain cancer, the eligibility criteria will further limit the pool of available trial participants as we will require that patients have specific characteristics, such as a certain severity or stage of disease progression, to include them in a trial. Additionally, the process of finding eligible patients may prove costly. We also may not be able to identify, recruit, and enroll a sufficient number of patients to complete our clinical trials because of the perceived risks and benefits of the product candidate under evaluation, the availability and efficacy of

competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, the availability of genetic sequencing information for patient tumors so that we can identify patients with the targeted genetic mutations, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed. The enrollment of patients further depends on many factors, including:

- the proximity of patients to clinical trial sites;
- patient referral practices of physicians;
- the design of the clinical trial, including the number of site visits and invasive assessments required;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- reporting of the preliminary results of any of our clinical trials;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion; and
- factors we may not be able to control, such as any future public health crisis, that may limit patient participation, hiring of principal investigators or staff or clinical site availability.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a clinical trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because certain of our product candidates represent a departure from more commonly used methods for cancer treatment and because certain of our product candidates have not been tested in humans before, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in any future clinical trial of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented.

Even if we receive marketing approval for our current or future product candidates, our current or future product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.

The commercial success of our current or future product candidates, if approved by the FDA or other applicable regulatory authorities, will depend upon the awareness and acceptance of our current or future product candidates among the medical community, including physicians, patients and healthcare payors. Market acceptance of our current or future product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy of our current or future product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared to other available medicines;
- limitations or warnings contained in the labeling approved for our current or future product candidates by the FDA or other applicable regulatory authorities;
- the prevalence and severity of adverse events associated with our product candidates or those products with which they may be co-administered in immuno-oncology and, in particular, viral immunotherapies;
- the clinical indications for which our current or future product candidates are approved;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the potential and perceived advantages of our current or future product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the willingness of the target patient populations to try new therapies or treatment methods and of physicians to prescribe these therapies or methods in immuno-oncology and, in particular, viral immunotherapies;
- the need to dose such product candidates in combination with other therapeutic agents, and related costs;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;

- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our current or future product candidates;
- our ability to obtain sufficient third-party coverage or reimbursement;
- the ability or willingness of patients to pay out-of-pocket in the absence of third-party coverage; and
- potential product liability claims.

If our current or future product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from our current or future product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our current or future product candidates, in addition to treating these target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community, patient organizations and third-party payors about the benefits of our current or future product candidates may require significant resources and may never be successful.

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

The development and commercialization of new product candidates is highly competitive. We face competition from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others with respect to CAN-2409 and CAN-3110 and will face similar competition with respect to any product candidates that we may seek to develop or commercialize in the future. We compete in pharmaceutical, biotechnology and other related markets that develop immuno-oncology therapies for the treatment of cancer. There are other companies working to develop viral immunotherapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. The large pharmaceutical and biotechnology companies that have commercialized and/or are developing immuno-oncology treatments for cancer include AstraZeneca, Bristol-Myers Squibb, Gilead Sciences, Merck, Novartis, Pfizer, Regeneron and Roche/Genentech.

Some of the products and therapies developed by our competitors are based on scientific approaches that are the same as or similar to our approach, including with respect to the use of viral immunotherapy with adenovirus and HSV. Other competitive products and therapies are based on entirely different approaches. We are aware that Replimune, TILT and ImmVira, among others, are developing viral immunotherapies that may have utility for the treatment of indications that we are targeting. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of the companies we compete against or may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in concentration of even more resources among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and enrolling subjects for our clinical trials and in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, or are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience and price, if required, the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors.

Risks Related to Government Regulation and Commercialization of Our Product Candidates

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize CAN-2409, CAN-3110 and future product candidates as expected, and our ability to generate revenue may be materially impaired.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. 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. These regulatory requirements may require us to amend our clinical trial protocols, including to comply with the protocols of any applicable SPA we receive from the FDA; conduct additional preclinical studies or clinical trials that may require regulatory or independent IRB approval; or otherwise cause delays in obtaining approval or rejection of an application. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which may materially harm our business, financial condition, results of operations, stock price and prospects.

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 studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. 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, and there may be varying interpretations of data obtained from preclinical studies or clinical trials, any of which may cause delays or limitations in the approval or a decision not to approve an application. It is possible that CAN-2409, CAN-3110 and future product candidates will never obtain the appropriate regulatory approvals necessary for us to commence product sales.

If we experience delays in obtaining approval, if we fail to obtain regulatory approval of CAN-2409, CAN-3110 or any future product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and our ability to generate revenues from that product candidate may be materially impaired.

CAN-2409, CAN-3110 or future product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any. Serious adverse events or undesirable side effects caused by CAN-2409, CAN-3110 and future product candidates could cause us, IRBs, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. For example, if concerns are raised regarding the safety of a new therapeutic as a result of undesirable side effects identified during clinical or preclinical testing, the FDA or comparable foreign regulatory authority may order us to cease further development, decline to approve the product candidate or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate. The FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, may also require, or we may voluntarily develop, strategies for managing adverse events during clinical development, which could include restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, or the monitoring of safety data by a data monitoring committee, among other strategies. For example, patients enrolled in our ongoing clinical trials of CAN-2409 and CAN-3110 have experienced mild to moderate adverse events, consisting mainly of flu-like symptoms and injection site reactions. In response to these adverse events, we have implemented prophylactic measures, including intravenous fluids, antiemetics and antipyretics. The FDA's or a comparable foreign regulatory authority's requests for additional data or information could also result in substantial delays in the approval of CAN-2409, CAN-3110 and future product candidates.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of a product candidate may only be uncovered when a significantly larger number of patients are exposed to the product candidate or when patients are exposed for a longer period of time.
Undesirable side effects caused by CAN-2409, CAN-3110 or any future product candidates could also result in denial of regulatory approval by the FDA or comparable foreign regulatory authorities for any or all targeted indications or the inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or may result in requirements for costly post-marketing testing and surveillance, or other requirements, including the submission of a Risk Evaluation and Mitigation Strategy (REMS) to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of CAN-2409, CAN-3110 and future product candidates. Any such limitations or restrictions could similarly impact any supplemental marketing approvals we may obtain for CAN-2409 and CAN-3110. Undesirable side effects may limit the potential market for any approved products or could result in restrictions on manufacturing processes, the discontinuation of the sales and marketing of the product, or withdrawal of product approvals. We could also be sued and held liable for harm caused to patients, or become subject to fines, injunctions or the imposition of civil or criminal penalties.

If CAN-2409, CAN-3110 and future product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain 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. The therapeutic-related side effects could affect patient recruitment or the

ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially harm our business, financial condition, results of operations, stock price and prospects.

The FDA's agreement to a Special Protocol Assessment with respect to the study design of our pivotal phase 3 clinical trial of CAN-2409 in newly diagnosed localized prostate cancer in intermediate and high-risk patients does not guarantee any particular outcome from regulatory review, including ultimate approval, and may not lead to a successful review or approval process.

We have obtained agreement from the FDA on the design and size of our pivotal phase 3 clinical trial of CAN-2409 in newly diagnosed localized prostate cancer in intermediate- and high-risk patients in combination with the SoC through a Special Protocol Assessment (SPA). The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs and biologics by allowing the FDA to evaluate the proposed design and size of certain clinical or animal studies, including clinical trials that are intended to form the primary basis for determining a product candidate's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding protocol design and scientific and regulatory requirements. The FDA aims to complete SPA reviews within 45 days of receipt of the request. The FDA ultimately assesses whether specific elements of the protocol design of the trial, such as entry criteria, dose selection, endpoints and/or planned analyses, are acceptable to support regulatory approval of the product with respect to the effectiveness of the indication studied. All exchanges between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA.

Although the FDA may agree to an SPA, an SPA agreement does not guarantee approval of a product. Even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. While we have obtained an SPA agreement for our phase 3 clinical trial, we have subsequently made minor amendments to the protocol and have not obtained an SPA amendment in connection with the amended protocol.

In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol. Generally, such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

Moreover, if the FDA revokes or alters its agreement under the SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval of CAN-2409 in prostate cancer.

A fast track designation by the FDA, even though granted for CAN-2409 and CAN-3110, or if received for any other future 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.

If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA fast track designation for a particular indication. We have been granted fast track designation for the use of CAN-2409 for: (1) the treatment of localized, primary prostate cancer in combination with radiation therapy to improve the local control rate; (2) with valacyclovir in combination with pembrolizumab in order to improve survival or delay progression in patients with stage III/IV NSCLC who are resistant to first line PD-(L)1 inhibitor therapy and who do not have activating molecular driver mutations; and (3) with prodrug (valacyclovir) for the treatment of patients with pancreatic ductal adenocarcinoma (PDAC) to improve overall survival. CAN-3110 was also granted fast track designation for the treatment of patients with recurrent high-grade glioma to improve overall survival. We may also seek fast track designation for certain of our future product candidates, as appropriate. However, there is no assurance that the FDA will grant this status to CAN-3110, CAN-2409, or any of our proposed product candidates. Marketing applications filed by sponsors of products in fast track development may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant fast track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even though we have received fast track designation for CAN-2409 and CAN-3110 or even if we receive fast track designation for our future product candidates or additional indications in CAN-2409 and CAN-3110, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a fast track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any fast track designation at any time.

A breakthrough therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek breakthrough therapy designation for some or all of our 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. Sponsors of product candidates that have been designated as breakthrough therapies are eligible to receive more intensive FDA guidance on developing an efficient drug development program, an organizational commitment involving senior managers, and eligibility for rolling review and priority review. Drugs and biologics 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 product candidates developed and considered for approval that have not received breakthrough therapy designation 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 CAN-2409, CAN-3110 or some or all of our future product candidates for the treatment of various cancers, there can be no assurance that we will receive breakthrough therapy designation.

We have received orphan drug designation from the FDA for CAN-2409 for the treatment of pancreatic cancer. We may seek orphan drug designation from regulatory authorities in other jurisdictions for CAN-2409, and we may seek orphan drug designation for our other product candidates. In any of these instances, we may not receive the requested designation or we may be unable to realize the benefits associated with orphan drug designation, including the potential for market exclusivity.

We have received orphan drug designation from the FDA for CAN-2409 for the treatment of pancreatic cancer. Even if CAN-2409 were to obtain orphan drug exclusivity for this use upon marketing approval by the FDA, the benefit of that exclusivity may be limited if the approval is in an indication that is broader than the orphan-designated indication, or exclusivity could be revoked under certain circumstances, for example if the FDA later determines that the request for designation was materially defective or if the sponsor is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, orphan drug exclusivity may not effectively protect the product from competition during the exclusivity period because different drugs with different active moieties can be approved for the same condition, and the same product can be approved for different uses. Also, the FDA may grant approval to the same drug for the same orphan indication if the second applicant can establish in its application that its product is safer, more effective or otherwise clinically superior to the previously approved product, or if the application holder of the previously approved product consents.

Accelerated approval by the FDA, even if granted for certain of our current or future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek approval of certain of our current or future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence by the sponsor and, under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is permitted to require, as appropriate, that such trials be underway prior to approval or within a specified time period after the date accelerated approval is granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such confirmatory trials, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such trials in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory trial or submit timely reports to the agency on their progress. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance that the product's accelerated approval will eventually be converted to a traditional FDA approval.

We may seek approval of our product candidate into Real-Time Oncology Review (RTOR). This program may not lead to a faster regulatory review or approval process and does not increase the likelihood that our product candidate(s) will receive marketing approval.

Participation in RTOR is voluntary. Our acceptance into RTOR does not guarantee or influence approval of our application, which is subject to the same statutory and regulatory requirements for approval as applications that are not included in RTOR. Although early approvals have occurred with applications selected for RTOR, this may not be the case for our application even if it is selected for RTOR. If at any time the FDA determines our participation in RTOR, if selected, is no longer appropriate, the FDA may rescind our acceptance and instruct us to follow routine submission procedures for marketing approval.

Even if our development efforts are successful, we may not obtain regulatory approval of CAN-2409, CAN-3110 or any future product candidates in the United States or other jurisdictions, which would prevent us from commercializing CAN-2409, CAN-3110 and future product candidates. Even if we obtain regulatory approval for CAN-2409, CAN-3110 and future product candidates, any such approval may be subject to limitations, including with respect to the approved indications or patient populations, which could impair our ability to successfully commercialize CAN-2409, CAN-3110 or any future product candidates.

We are not permitted to market or promote or sell CAN-2409, CAN-3110 or any future product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by the regulatory authorities. If we do not receive approval from the FDA and comparable foreign regulatory authorities for any of CAN-2409, CAN-3110 and future product candidates, we will not be able to commercialize such product candidates in the United States or in other jurisdictions. If significant delays in obtaining approval for and commercializing CAN-2409, CAN-3110 and future product candidates occur in any jurisdictions, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Even if CAN-2409, CAN-3110 and future product candidates are approved, they may:

- be subject to limitations on the indicated uses or patient populations for which they may be marketed, distribution restrictions, or other conditions of approval;
- not be approved with label statements necessary or desirable for successful commercialization; or
- contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a REMS, to monitor the safety or efficacy of the products.

We have not previously submitted a Biologics License Application (BLA), to the FDA, or a similar marketing application to comparable foreign regulatory authorities, for CAN-2409, CAN-3110 or any product candidate, and we can provide no assurance that we will ultimately be successful in obtaining regulatory approval for claims that are necessary or desirable for successful marketing, if at all.

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

As product candidates are developed through preclinical studies to later-stage clinical trials towards 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 processes and results. Any of these changes could cause CAN-2409, CAN-3110 or any future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Changes in third-party manufacturers and manufacturing processes may also require additional testing, or notification to, or approval by the FDA or a comparable foreign regulatory authority. Such changes could be further delayed due to development of clinical-scale manufacturing and commercial-scale manufacturing operations. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of CAN-2409, CAN-3110 and future product candidates and jeopardize our ability to commence product sales and generate revenue.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. 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 and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. federal government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government 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. A potential U.S. federal government shutdown may also increase uncertainty and volatility in the global economy and financial markets, which could negatively impact 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.

Even if CAN-2409, CAN-3110 or any future product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products.

Any product candidate for which we may obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA and comparable foreign regulatory authorities, including requirements related to the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with current good manufacturing practice (cGMP), requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and good clinical practices (GCPs), for any clinical trials that we conduct post-approval.

The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of CAN-2409, CAN-3110 and future product candidates, they may withdraw approval, issue public safety alerts, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

We and any of our suppliers or collaborators, including our CDMOs, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes.

In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with any products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various negative results, including:

- restrictions on manufacturing, distribution, or marketing of such products;
- restrictions on the labeling, including required additional warnings, such as boxed warnings, contraindications, precautions, and restrictions on the approved indication or use;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- modifications to promotional pieces;
- issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or similar strategy;
- changes to the way the product is administered to patients;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning or untitled letters;

•suspension of marketing or withdrawal of the products from the market;

•regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product;

•refusal to approve pending applications or supplements to approved applications that we submit;

•recalls of products;

•fines, restitution or disgorgement of profits or revenues;

•suspension or withdrawal of marketing approvals;

•refusal to permit the import or export of our products;

•product seizure or detention;

•FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or

•injunctions or the imposition of civil, criminal or administrative penalties, including imprisonment.

Any of these events could prevent us from achieving or maintaining market acceptance of any particular product or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its marketing and sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

Further, the FDA's policies or those of comparable foreign regulatory authorities may change and could impose extensive and ongoing regulatory requirements and obligations on any product candidate for which we obtain marketing approval. 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 be subject to regulatory enforcement action, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions or other enforcement actions if we are determined to be promoting the use of our products for unapproved or "off-label" uses, or in a manner inconsistent with the approved labeling, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, the Office of Inspector General for the Department of Health and Human Services (HHS), state attorneys general, members of Congress and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for desired uses or indications for CAN-2409, CAN-3110 and future product candidates, we may not market or promote them for those indications and uses, referred to as off-label uses, and our business, financial condition, results of operations, stock price and prospects will be materially harmed. We also must sufficiently substantiate any claims that we make for any products, including claims comparing those products to other companies' products, and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

Physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off-label use.

If we are found to have impermissibly promoted any of CAN-2409, CAN-3110 and future product candidates, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion 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. In the United States, engaging in the impermissible promotion of any products, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines,

agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These False Claims Act lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements pertaining to certain sales practices and promoting off-label uses. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payers based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

In the United States, the promotion of biopharmaceutical products is subject to additional FDA requirements and restrictions on promotional statements. If, after CAN-2409, CAN-3110 or any future product candidates obtains marketing approval, the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities, and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We may not be able to file INDs or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or a comparable foreign regulatory may not permit us to proceed.

The FDA or comparable foreign regulatory authorities may require us to file separate INDs for additional clinical trials we plan to conduct with our current most advanced product candidates, CAN-2409 and CAN-3110. We may not be able to file any additional INDs required for our current product candidates and any future product candidates on the timelines we expect. For example, we may experience delays if we are unable to access earlier data from inactive or withdrawn INDs. Moreover, we cannot be sure that submission of an IND will result in the FDA or comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their 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 expected timelines to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. There are similar risks related to the review and authorization of our protocols and amendments by comparable foreign regulatory authorities.

If approved, our investigational products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

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

We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened or unavailable due to congressional action, a determination that approval of one of our candidates does not constitute "first licensure" or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.
If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

Our current and future target patient populations are based on our beliefs and estimates regarding the incidence or prevalence of certain types of the indications that may be addressable by our product candidates, which is derived from a variety of sources, including scientific literature and surveys of clinics. Our projections may prove to be incorrect and the number of potential patients may turn out to be lower than expected. The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access, the success of competing therapies and product pricing and reimbursement. Further, the market opportunity for viral immunotherapies is hard to estimate given that it is an emerging field with few globally or FDA-approved therapies, none of which have yet to enjoy broad market acceptance. Even if we obtain significant market share for our product candidates, because the potential target populations could be small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Healthcare reform measures may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current or future product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Among policy-makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. For more information, see "*Business – Health Reform*" in our Annual Report on Form 10-K for the year ended December 31, 2023.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical and biologic 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.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices.

We expect that the healthcare reform measures that have been adopted and 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 and could seriously harm our future revenues. 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 products.

If, in the future, we are unable to establish sales and marketing and patient support capabilities or enter into agreements with third parties to sell and market our current or future product candidates, we may not be successful in commercializing our current or future product candidates if and when they are approved, and we may not be able to generate any revenue.

We do not currently have a sales or marketing infrastructure and have limited experience in the sales, marketing, patient support or distribution of products. To achieve commercial success for any approved product candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, patient support, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. In the future, we may choose to build a focused sales and

marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our current or future product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing and patient support capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any drug launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our current or future product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to use any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing, patient support and distribution services, our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any current or future product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our current or future product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our current or future product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our current or future product candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

If any product candidate for which we receive regulatory approval does not achieve broad market acceptance among physicians, patients, healthcare payors, and the medical community, the revenues that we generate from its sales will be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, and others in the medical community. Commercial success also will depend, in large part, on the coverage and reimbursement of our product candidates by third-party payors, including private insurance providers and government payors. The degree of market acceptance of any approved product would depend on a number of factors, including:

- the efficacy, safety and tolerability as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of cancer or neurology clinics and patients of the product as a safe, tolerable and effective treatment;
- the potential and perceived advantages of the product candidate over alternative treatments;
- the safety and tolerability of the product candidate in a broader patient group;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement by third party payors and government authorities;
- changes in regulatory requirements by government authorities for the product candidate;
- relative convenience and ease of administration;
- the prevalence and severity of side effects and adverse events;
- the effectiveness of our sales and marketing efforts; and
- favorable or unfavorable publicity relating to the product or relating to the Company.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and we may not become profitable, which would have a material adverse effect on our business.

If we fail to develop additional product candidates, our commercial opportunity could be limited.

We expect initially to develop our most advanced product candidates, CAN-2409 and CAN-3110. A key part of our strategy, however, is to pursue clinical development of additional product candidates. Developing, obtaining marketing approval for, and commercializing additional product candidates will require substantial additional funding and will be subject to the risks of failure inherent in medical product development. We cannot assure you that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market additional product candidates for the treatment of solid tumors, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any drugs on the market, if we begin commercializing our current or future product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any current or future product candidates for which we obtain marketing approval. Our future arrangements with 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 market, sell and distribute our current or future product candidates for which we obtain marketing approval.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge and may not comply under one or more of such laws, regulations and guidance. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results.

We may face potential liability if we obtain identifiable patient health information from clinical trials sponsored by us.

Most healthcare providers, including certain research institutions from which we may obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, 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 criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, in the future, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who may enroll in patient assistance programs if we choose to implement such programs. As such, we may be subject to state laws requiring 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.

Foreign data protection laws, including the European Union's General Data Protection Regulation (the EU GDPR), and the United Kingdom (or UK) equivalent of the same (the UK GDPR, together with the EU GDPR, the GDPR) may also apply to our processing of health-related and other personal data.

The GDPR imposes stringent requirements for controllers and processors of personal data of individuals within the European Economic Area (the EEA) or the UK. The GDPR applies to any company established in the EEA or UK as well as to those outside the EEA or UK if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or UK or the monitoring of their behavior. The GDPR, together with national legislation, regulations and guidelines of the EEA Member States and the UK governing the processing of personal data, impose strict obligations and restrictions on the

ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the UK, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million (£17.5 million) or 4% of the annual global revenues of the noncompliant company, whichever is greater. Currently, the EU GDPR and UK GDPR remain largely aligned, but the UK has announced plans to reform the country's data protection legal framework in its Data Reform Bill, which will introduce significant changes from the EU GDPR. This may lead to additional compliance costs and could increase our overall risk exposure as we may no longer be able to take a unified approach across the EEA and the UK, and we will need to amend our processes and procedures to align with the new framework.

The GDPR also imposes restrictions in relation to the international transfer of personal data from the EEA and UK and other countries in respect of which the European Commission or the UK government has not issued a so-called "adequacy decision" or "adequacy regulation" (known as "third countries"), unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. This includes putting in place the European Commission's Standard Contractual Clauses for transfers outside of the EEA and a similar transfer mechanism for transfers of personal data outside of the UK, the International Data Transfer Agreement or Addendum (IDTA). Under both the EU GDPR and the UK GDPR, exporters are also required to assess the risk of the data transfer on a case-by-case basis, including an analysis of the laws in the destination country.

In July 2023, the European Commission adopted its adequacy decision for the EU-U.S. Data Privacy Framework (Framework), the successor of the EU-U.S. Privacy Shield framework, which the Court of Justice of the European Union invalidated in 2020. On the basis of the new adequacy decision, personal data can flow safely from the EU to U.S. companies participating in the Framework, without having to put in place additional data protection safeguards. However, the Framework has already been challenged in European courts, which may lead to its invalidation.

Implementing mechanisms to endeavor to ensure compliance with the GDPR and relevant local legislation in EEA Member States and the UK may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations, and prospects. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, and orders to cease/change our use of data, enforcement notices, or potential civil claims including class action-type litigation.

In addition, governments in the United States are increasingly passing stringent privacy laws. California recently enacted and has proposed companion regulations to the California Consumer Privacy Act (CCPA), which went into effect January 1, 2020. The CCPA creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. As of March 28, 2020, the California State Attorney General has proposed varying versions of companion draft regulations which are not yet finalized. Despite the delay in adopting regulations, the California State Attorney General commenced enforcement actions against violators on July 1, 2020. While there are currently exceptions for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. On August 14, 2020, implementing regulations were finalized and became effective as of that date. While clinical trial data and information governed by HIPAA are currently exempt from the current version of the CCPA, other personal information may be applicable and possible changes to the CCPA may broaden its scope. We continue to monitor the impact the CCPA may have on our business activities.

Additionally, a new California ballot initiative, the California Privacy Rights Act (CPRA) was passed in November 2020. Effective starting on January 1, 2023, the CPRA imposes additional obligations on companies covered by the legislation and will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. The effects of the CCPA and the CPRA are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and/or litigation.

Also, on March 2, 2021, Virginia enacted the Consumer Data Protection Act (CDPA). The CDPA will become effective January 1, 2023. The CDPA will regulate how businesses, which the CDPA refers to as "controllers", collect and share personal information. The law applies to companies that conduct business in Virginia or product products or services that are targeted to residents of Virginia and either: (1) annually control or process personal data of at least 100,000 Virginia residents; or (2) control or process the personal data of at least 25,000 Virginia residents and derive over 50% of gross revenue from the sale of personal data. While the CDPA incorporates many similar concepts of the CCPA and CPRA, there are also several key differences in the scope, application, and enforcement of the law that will change the operational practices of controllers. The new law will impact how controllers collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. In addition, on July 8, 2021, Colorado's governor signed the

Colorado Privacy Act (CPA) into law. The CPA is rather similar to the Virginia's CPDA but also contains additional requirements. The new measure applies to companies conducting business in Colorado or who produce or deliver commercial products or services intentionally targeted to its residents of the state and that either: (1) control or process the personal data of at least 100,000 Colorado residents during a calendar year; or (2) derive revenue or receive a discount on the price of goods or services from the sale of personal data and process or control the personal data of at least 25,000 Colorado residents.

Moreover, on March 24, 2022, Utah's governor signed the Utah Consumer Privacy Act (UCPA) into law. The UCPA will take effect on December 31, 2023. Also, in May 2022, Connecticut Governor Lamont signed the Connecticut Data Privacy Act (CTDPA) into laws. The UCPA and CTDPA draw heavily upon their predecessors in Virginia and Colorado. With the CTDPA, Connecticut became the fifth state to enact a comprehensive privacy law. New privacy and data security laws have been proposed in more than half of the states in the U.S. and in the U.S. Congress. With bills proposed in many other jurisdictions, it remains quite possible that other states will follow suit. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country will make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

The increasing number and complexity of regional, country and U.S. state data protection laws, and other changes in laws or regulations across the globe, especially those associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could lead to government enforcement actions and significant penalties against us and could have a material adverse effect on our business, financial condition or results of operations

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Patients about whom we or our collaborators may obtain health information, as well as the providers who may share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy 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.

If we or third-party contract research organizations (CROs) or other contractors or consultants fail to comply with applicable federal, state/provincial or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our therapeutic candidates and could harm or prevent sales of any affected therapeutics that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our therapeutics. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.
Additionally, we are subject to other state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

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 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.

Risks Related to Employee Matters, Managing Growth and General Business Operations

Any future public health crisis may affect our ability to complete our ongoing clinical trials and initiate and complete other preclinical studies, planned clinical trials or future clinical trials, disrupt regulatory activities, disrupt our manufacturing and supply chain or have other adverse effects on our business and operations. In addition, any future

public health crisis may cause substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business, operations and ability to raise capital.

Any future public health crisis may cause governments to implement measures to slow the spread of the public health crisis through quarantines, travel restrictions, heightened border scrutiny and other measures. Government measures taken in response to any future public health crisis may also have a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages may occur; supply chains may be disrupted; facilities and production may be suspended; and demand for certain goods and services, such as medical services and supplies, may spike, while demand for other goods and services, such as travel may fall. The extent to which any future public health crisis may in the future have an impact on our operations or those of the third parties on which we rely depends on many factors, which are highly uncertain and cannot be predicted with confidence. Additionally, the conduct of our clinical trials, preclinical studies and manufacturing activities is dependent upon the availability of clinical trial sites, CROs, CDMOs, researchers and investigators, regulatory agency personnel and logistics providers, all of which may in the future be adversely affected by any future public health crisis.

Any negative impact that any future public health crisis may have on enrolling or retaining patients in our clinical trials, the ability of our suppliers to provide materials for our product candidates, or the regulatory review process could cause delays with respect to product development activities, which could materially and adversely affect our ability to obtain marketing approval for and to commercialize our product candidates, increase our operating expenses, affect our ability to raise additional capital, and have a material adverse effect on our financial results.

Any future public health crisis may cause disruptions in the future, which could adversely impact our ability to raise additional funds through public offerings or private placements and may also impact the volatility of our stock price and trading in our stock. Moreover, it is possible that any future public health crisis could impact economies worldwide, which could result in adverse effects on our business and operations.

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

We are highly dependent on the research and development, clinical, financial, operational and other business expertise of our executive officers, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing personnel will also be critical to our success. On December 11, 2023, Jason A. Amello resigned from his position as our Chief Financial Officer, principal financial officer and principal accounting officer, effective January 12, 2024. Mr. Amello will remain an advisor to us in order to support the transition of his responsibilities. On January 12, 2024, our board of directors unanimously appointed Charles Schoch as the Company’s interim Chief Financial Officer, principal financial officer and principal accounting officer, effective January 12, 2024.

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

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

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities. We expect the number of our employees and the scope of our operations to grow, particularly in the areas of drug development, clinical, regulatory affairs and, if any product candidate receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The

expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biotechnology and biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities and heightened scrutiny by the FDA, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding our company, management, product candidates or products. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Our internal computer systems, or those of our third-party CROs that we may use in the future, or other contractors or consultants, may fail or suffer security incidents, which could result in a material disruption of our product candidates' development programs.

Despite our implementation of security measures, our internal computer systems, and those of our CROs that we may use in the future, information technology suppliers and other contractors and consultants are vulnerable to damage from computer viruses, cyberattacks and other unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security incident were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any of our product candidates could be delayed. In addition, our liability and cyber insurance may not be sufficient in type or amount to cover us against claims related to security incidents, cyber-attacks or other related liabilities.

Cyberattacks are increasing in their frequency, sophistication, and intensity, and are becoming increasingly difficult to detect. They are often carried out by well-resourced and skilled parties, including nation states, organized crime groups, "hacktivists" and employees or contractors acting carelessly or with malicious intent. Cyber-attacks include deployment of harmful malware and key loggers, ransomware, denial-of-service attacks, malicious websites, the use of social engineering (including phishing attacks), and other means to affect the confidentiality, integrity and availability of our technology systems and data. Cyber-attacks also include manufacturing, hardware or software supply chain attacks, which could cause a delay in the manufacturing of products or products produced for contract manufacturing or lead to a data privacy or security incident. Our business partners face similar risks, and any security incident related to their systems could adversely affect our security or the security of our systems or data. In addition, our increased use of cloud technologies heightens these third party and other operational risks, and any failure by cloud or other technology service providers to adequately safeguard their systems and prevent cyber-attacks could disrupt our operations and result in misappropriation, corruption, or loss of confidential or propriety information. Risk of cyber-attack is increased with employees working remotely. Remote work increases the risk we may be vulnerable to cybersecurity-related events such as phishing attacks and other security threats.

Although we develop and maintain systems and controls designed to prevent these events from occurring, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security incident, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

If a material security incident related to our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our cybersecurity measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks, including costs to deploy additional personnel and protection technologies, train employees, and engage third-party experts and consultants, which could materially and adversely affect our business, financial condition and results of operations. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private

litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices.

Our operations or those of the third parties upon whom we depend might be affected by the occurrence of a natural disaster, pandemic, war or other catastrophic event.

We depend on our employees and consultants, CDMOs and CROs that we may use in the future, as well as regulatory agencies and other parties, for the continued operation of our business. While we maintain disaster recovery plans, they might not adequately protect us. Despite any precautions we take for natural disasters or other catastrophic events, these events, including terrorist attacks, pandemics, wars hurricanes, fire, floods and ice and snowstorms, could result in significant disruptions to our research and development, preclinical studies, clinical trials, and, ultimately, commercialization of our products. Long-term disruptions in the infrastructure caused by events, such as natural disasters, the outbreak of war, the escalation of hostilities and acts of terrorism or other "acts of God," particularly involving cities in which we have offices, manufacturing or clinical trial sites, could adversely affect our businesses. For example, in late February 2022, Russian military forces launched significant military action against Ukraine, and sustained conflict and disruption in the region is likely. The impact to Ukraine, as well as actions taken by other countries, including new and stricter sanctions by Canada, the United Kingdom, the European Union, the United States and other countries and organizations against officials, individuals, regions, and industries in Russia, Ukraine and Belarus, and each country's potential response to such sanctions, tensions, and military actions could have an adverse effect on the Company's operations. These countries may impose further sanctions or other restrictive actions against governmental or other individuals or organizations in Russia or elsewhere. In addition, in October 2023, Hamas launched an attack on Israel, and Israel declared war on Hamas, with the armed conflict ongoing as of the date of this filing. The effects of disruptive events could affect the global economy and financial and commodities markets in ways that cannot necessarily be foreseen at the present time. Although we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, our coverage might not respond or be adequate to compensate us for all losses that may occur. Any natural disaster or catastrophic event affecting us, our CDMOs or CROs, regulatory agencies or other parties with which we are engaged could have a significant negative impact on our operations and financial performance.

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

As a public company, we are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If we identify material weaknesses in our internal control over financial reporting in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and the market price of our common stock.

We are subject to the requirements of the Sarbanes-Oxley Act and the applicable SEC rules and regulations that require an annual management report on our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We cannot assure you that we will not identify material weaknesses in our internal control over financial reporting. In addition, our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting in accordance with the provisions of the SOX Act because no such evaluation has been required. Had our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the SOX Act, one or more material weaknesses may have been identified. If future material weaknesses are identified in our internal control over financial reporting, or if we otherwise fail to maintain an effective system of internal controls, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and the market price of our common stock may decline as a result.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management are required to assess the effectiveness of these controls annually. However, for as long as we are an EGC under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an EGC for up to five years. Our assessment of internal controls and procedures may not detect material weaknesses in our internal control over financial reporting. Material weaknesses in our internal control over financial reporting may go undetected and could lead to financial statement restatements and require us to incur the expense of remediation, which could have a negative effect on the trading price of our stock.

Risks Related to Legal and Compliance Matters

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability and have to limit the commercialization of any approved products and/or our product candidates.

The use of our product candidates in clinical trials, and the sale of any product for which we obtain regulatory approval, exposes us to the risk of product liability claims. We face inherent risk of product liability related to the testing of our product candidates in human clinical trials, including liability relating to the actions and negligence of our investigators, and will face an even greater risk if we commercially sell any product candidates that we may develop. For example, we may be sued if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against us by consumers, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates;
- significant negative media attention;
- decreases in our stock price;
- initiation of investigations and enforcement actions by regulators; and
- product recalls, withdrawals or labeling, marketing or promotional restrictions, including withdrawal of marketing approval.

We believe we have sufficient insurance coverage in place for our business operations. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain FDA or comparable foreign regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing, or at all. Failure to obtain and retain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of products we develop. On occasion, large judgments have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. A successful product liability claim or series of claims

brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash, and materially harm our business, financial condition, results of operations, stock price and prospects.

We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as import and export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, financial condition, results of operations, stock price and prospects.

Our operations are subject to anti-corruption laws, including the Foreign Corrupt Practices Act (FCPA), and other anti-corruption laws that apply in countries where we do business. The FCPA and these other laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We also may participate in collaborations and relationships with third parties whose actions, if non-compliant, could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.
We are also subject to other laws and regulations governing our international operations, including regulations administered by the government of the United States, including applicable import and export control regulations, economic sanctions on countries and persons, anti-money laundering laws, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

We can provide no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws or other legal requirements, including trade control laws. If we are not in compliance with applicable anti-corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, stock price and prospects. Likewise, any investigation of any potential violations of these anti-corruption laws or trade control laws by United States or other authorities could also have an adverse impact on our reputation, our business, financial condition, results of operations, stock price and prospects.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health and other information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We are subject to many federal and state healthcare laws, such as the federal Anti-Kickback Statute, the federal civil and criminal False Claims Acts, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the Veterans Health Care Act of 1992 (VHCA), HIPAA, the FCPA, the ACA and similar state laws. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws, and regulations pertaining to fraud and abuse, reimbursement programs, government procurement, and patients' rights are and will be applicable to our business. We would be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. In the European Union, the data privacy laws are generally stricter than those which apply in the United States and include specific requirements for the collection of personal data of European Union persons or the transfer of personal data outside of the European Union to the United States to ensure that European Union standards of data privacy will be applied to such data. For more information, see "*Business – Other Healthcare Laws and Compliance Requirements*" in our Annual Report on Form 10-K for the year ended December 31, 2023.

If we or our operations, including our arrangements with physicians and other healthcare providers, some of whom receive share options or other financial interest in the business as compensation for services provided, are found to be in violation of any federal or state healthcare law, or any other governmental laws or regulations that apply to us, we may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, it or they may be subject to criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially affect our business.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal, state and foreign privacy, data protection, security, reimbursement, and fraud laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. 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 laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and 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. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

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

Changes in tax law may adversely affect our business or financial condition. Any new taxes could adversely affect our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, under Section 174 of the Internal Revenue Code of 1986, as amended (the Code), in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. In addition, it is uncertain if and to what extent various states will conform to changes to U.S. federal income tax law. We urge prospective investors in our common stock to consult with their legal and tax advisors with respect to any recently enacted tax legislation, or proposed changes in law, and the potential tax consequences of investing in or holding our common stock.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership by 5% stockholders over a three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income may be limited. As a result of our most recent private placements, the initial public offering (the IPO), and other transactions that have occurred over the past three years, we may have experienced, an “ownership change.” We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2023, we had U.S. federal and state net operating loss carryforwards of $86.2 million and $79.6 million, which begin to expire in 2027 and 2032, respectively, and which could be limited if we experience an “ownership change.” The reduction of the corporate tax rate under TCJA may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under current federal tax law, federal net operating losses generated after December 31, 2017 will not be subject to expiration but will not be permitted to be carried back. In addition, under current U.S. federal tax law, the amount of net operating losses generated after December 31, 2017 that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the net operating loss deduction itself. Additionally, as of December 31, 2023, we had a U.S. federal net operating loss carryforward of $77.4 million which do not expire but is limited to an annual deduction equal to 80% of annual taxable income.

If third-party payors fail to provide adequate coverage, reimbursement and payment rates for our product candidates, or if health maintenance organizations or long-term care facilities choose to use therapies that are less expensive or considered a better value, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, sales of our products will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers, and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new therapeutic products when more established or lower cost therapeutic alternatives are already available or subsequently become available, even if our products are alone in a class. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and 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 a market share sufficient to realize a sufficient return on our or their investments. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost. For more information, see “*Business – Coverage and Reimbursement*” in our Annual Report on Form 10-K for the year ended December 31, 2023.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved therapeutics. Marketing approvals, pricing, and reimbursement for new therapeutic products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a therapeutic before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign

markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our or their investment in one or more product candidates, even if our product candidates obtain marketing approval. Our ability to commercialize our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Regulatory authorities and third-party payors, such as private health insurers, and health maintenance organizations, decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Several third-party payors are requiring that companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes, are disregarding therapeutic differentiators within classes, are challenging the prices charged for therapeutics, and are negotiating price concessions based on performance goals.

Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. If payors subject our product candidates to maximum payment amounts, or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may seek alternative therapies. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

In addition, federal programs impose penalties on manufacturers of therapeutics in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. A few states have also passed or are considering legislation intended to prevent significant price increases. Regulatory authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us to decrease, discount, or rebate a portion of the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the realized prices for our products, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

In addition, third-party payors are increasingly requiring higher levels of evidence of the benefits and clinical outcomes of new technologies, benchmarking against other therapies, seeking performance-based discounts, and challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Our employees, independent contractors, consultants, commercial partners, principal investigators, CROs or CDMOs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, principal investigators, CDMOs or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act case against us even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, stock price and prospects, including the imposition of significant fines or other sanctions.

On March 15, 2024, we notified Dr. Aguilar-Cordova that we had uncovered that, during his tenure as Chief Executive Officer and possibly his tenure as Chief Scientific Officer, he allegedly (i) instructed company personnel to falsify sterility testing results

that were submitted to the FDA for CAN-2409 and (ii) failed to implement an appropriate and compliant stability testing program for that same program. Upon identifying these deficiencies, we promptly updated our stability testing program to fully bring it into compliance and submitted additional information and data to the FDA regarding both the updated program and our prior testing results. Following an internal review and analysis, we also determined that trial participants who were dosed with CAN-2409 were not placed at risk, and that there was and is no risk to the integrity of our resulting clinical data related to the identified deficiencies. In the March 15, 2024 letter, we also requested that Dr. Aguilar-Cordova resign from the board of directors with immediate effect. On March 26, 2024, Dr. Aguilar-Cordova denied these allegations in response.

Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other 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, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. 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 would incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third-party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, 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.

Risks Related to Our Reliance on Third Parties

For certain product candidates, we depend, or will depend, on development and commercialization collaborators to develop and conduct clinical trials with, obtain regulatory approvals for, and if approved, market and sell product candidates. If such collaborators fail to perform as expected, the potential for us to generate future revenue from such product candidates would be significantly reduced and our business would be harmed.

For certain product candidates, we depend, or will depend, on our development and commercial collaborators to develop, conduct clinical trials of, and, if approved, commercialize product candidates. We cannot provide assurance that our collaborators will be successful in or that they will devote sufficient resources to these collaborations. If our current or future collaboration and commercialization partners do not perform in the manner we expect or fail to fulfill their responsibilities in a timely manner, or at all, if our agreements with them terminate or if the quality or accuracy of the clinical data they obtain is compromised, the clinical development, regulatory approval and commercialization efforts related to their and our product candidates and products could be delayed or terminated and it could become necessary for us to assume the responsibility at our own expense for the clinical development of such product candidates. Moreover, our ability to generate revenues from these collaborations and product candidates will depend on such collaborators' abilities to perform in the manner we expect or fulfill their responsibilities in a timely manner, and delays by collaborators, or caused by other collaboration contract obligations, may result in a delay of our ability to disclose data.

Our current collaborations and any future collaborations that we enter into are subject to numerous risks, including:

- collaborators have significant discretion in determining the efforts and resources that they will apply to the collaborations;
- collaborators may not perform their obligations as expected or fail to fulfill their responsibilities in a timely manner, or at all;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on preclinical studies or clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay preclinical studies or clinical trials, provide insufficient funding for clinical trials, stop a preclinical study or 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 fail to make timely regulatory submissions for a product candidate;

•we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates;

•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;

•the collaborations may not result in product candidates to develop and/or preclinical studies or clinical trials conducted as part of the collaborations may not be successful;

•product candidates developed with collaborators may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to stop commercialization of our product candidates;

•a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate; and

•collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation.

In addition, certain collaboration and commercialization agreements provide our collaborators with rights to terminate such agreements, which rights may or may not be subject to conditions, and which rights, if exercised, would adversely affect our product development efforts and could make it difficult for us to attract new collaborators. For example, our license agreement with MGB may be terminated by MGB for our failure to pay, our failure to maintain proper insurance in accordance with the agreement, if we file for bankruptcy or if we remain in default for non-financial reasons following a specified cure period to remedy the breach. In the event of the termination of any collaboration or commercialization agreement, we would likely be required to limit the size and scope of efforts for the development and commercialization of such product candidates or products; we would likely be required to seek additional financing to fund further development or identify alternative strategic collaborations; our potential to generate future revenue from royalties and milestone payments from such product candidates or products would be significantly reduced, delayed or eliminated; and it could have an adverse effect on our business and future growth prospects. Our rights to recover tangible and intangible assets and intellectual property rights needed to advance a product candidate or product after termination of a collaboration may be limited by contract, and we may not be able to advance a program post-termination.

As a result of the foregoing, our current and any future collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If conflicts arise with our development and commercialization collaborators or licensors, they may act in their own self-interest, which may be adverse to the interests of our company.

We may in the future experience disagreements with our development and commercialization collaborators or licensors. Conflicts may arise in our collaboration and license arrangements with third parties due to one or more of the following:

•disputes with respect to milestone, royalty and other payments that are believed due under the applicable agreements;

•disagreements with respect to the ownership of intellectual property rights or scope of licenses;

•disagreements with respect to the scope of any reporting obligations;

•disagreements with respect to contract interpretation or the preferred course of development;

•unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities, or to permit public disclosure of these activities; and

•disputes with respect to a collaborator's or our development or commercialization efforts with respect to our products and product candidates.

Conflicts with our development and commercialization collaborators or licensors could materially adversely affect our business, financial condition or results of operations and future growth prospects.

We rely on third parties, including independent clinical investigators and CROs to conduct and sponsor some of the clinical trials of our product candidates. Any failure by a third party to meet its obligations with respect to the clinical development of our product candidates may delay or impair our ability to obtain regulatory approval for our product candidates.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, academic partners, medical institutions, regulatory affairs consultants and third-party CROs, to conduct our preclinical studies and clinical trials, including in some instances sponsoring such clinical trials, and to engage with regulatory authorities and monitor and manage data for our ongoing preclinical and clinical programs. While we have, or will have, agreements governing the activities of such third parties, we will control only certain aspects of their activities and have limited influence over their actual performance.

Any of these third parties may terminate their engagements with us under certain circumstances. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new contract research organization begins work. As a result, delays would likely occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

We remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we fail to exercise adequate oversight over any of our academic partners or CROs or if we or any of our academic partners or CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon a regulatory inspection of us, our academic partners or our CROs or other third parties performing services in connection with our clinical trials, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, 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, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

In addition, with respect to investigator-sponsored trials that are being or may be conducted, we do not control the design or conduct of these trials, and it is possible that the FDA or EMA will not view these investigator-sponsored trials as providing adequate support for future clinical trials or market approval, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. We expect that such arrangements will provide us certain information rights with respect to the investigator-sponsored trials, including the ability to obtain a license to obtain access to use and reference the data, including for our own regulatory submissions, resulting from the investigator-sponsored trials. However, we do not have control over the timing and reporting of the data from investigator-sponsored trials, nor do we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected. Additionally, the FDA or EMA may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA or EMA may require us to obtain and submit additional preclinical, manufacturing, or clinical data.

If the manufacturers upon which we may rely fail to produce our product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face

delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.

We also expect to develop commercial-scale manufacturing at third-party manufacturers for our product candidate CAN-2409. We may develop clinical manufacturing capabilities for CAN-3110 at third-party manufacturers. There can be no assurance that our supply of clinical product will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our CDMOs could require significant effort and expertise because there may be a limited number of qualified replacements. Any delays in obtaining adequate supplies of our product candidates that meet the necessary quality standards, including delays caused by any future public health crisis, may delay our development or commercialization.

We may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our product candidates or programs. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing and filling our viral product for us and willing to do so. If our existing third-party manufacturers, or the third parties that we engage in the future, should cease to work with us, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the therapeutic substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. Further, even if we do establish such collaborations or arrangements, our third-party manufacturers may breach, terminate, or not renew these agreements.

Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate or component may result in a delay in product development timelines and FDA or comparable foreign regulatory authority approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost and quality, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

The manufacture of biopharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of therapeutics often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state, and foreign regulations. Our CDMOs may not perform as agreed. If our manufacturers were to encounter these or other difficulties, our ability to provide product candidates to patients in our clinical trials could be jeopardized.

CDMOs of our product candidates may be unable to comply with our specifications, applicable cGMP requirements or other FDA, state or foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. Any such deviations may also require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. Any delays in obtaining products or product candidates that comply with the applicable regulatory requirements may result in delays to clinical trials, product approvals, and commercialization. It may also require that we conduct additional studies.

While we are ultimately responsible for the manufacturing of our product candidates and therapeutic substances, other than through our contractual arrangements, we have little control over our manufacturers' compliance with these regulations and standards. If the FDA 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 may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. We must also receive approval from the FDA and applicable comparable foreign regulatory authorities for the use of any new manufacturers for commercial supply. The regulatory authorities may also require additional studies if a new manufacturer is relied upon for commercial production. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product or product candidate according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CDMO

could negatively affect our ability to develop product candidates or once approved, to commercialize those product candidates in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. Accordingly, switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

A failure to comply with the applicable regulatory requirements, including periodic regulatory inspections, may result in regulatory enforcement actions against our manufacturers or us (including fines and civil and criminal penalties, including imprisonment) suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the product candidate, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, withdrawal of product approval, environmental or safety incidents and other liabilities. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Any failure or refusal to supply our product candidates or components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

Some of our product candidates are being and may be studied in third-party research and clinical trials sponsored by organizations or agencies other than us, or in investigator-sponsored clinical trials, which means we will have minimal or no control over the conduct of such trials and which may adversely affect our ability to obtain marketing approval or certain regulatory exclusivities.

We have supplied and may continue to supply and otherwise support third party research, including investigator-sponsored clinical trials. Investigator-sponsored clinical trials pose similar risks as those set forth elsewhere in this "Risk Factors" section relating to our internally-sponsored clinical trials, but because we are not be the sponsors of these trials, we have less control over the protocols, administration or conduct of these trials, including follow-up with patients and ongoing collection of data after treatment. Additionally, third party clinical research has been and may continue to be conducted with CAN-3110 and CAN-2409 which was not provided by us. The conduct or findings of these trials may have a negative impact on our development programs notwithstanding that we have little involvement or control over these trials. As a result, we are subject to additional risks associated with the way investigator-sponsored trials are conducted. In particular, for trials in which we supply drug product, we may be named in lawsuits that would lead to increased costs associated with legal defense. Additional risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data. Third-party investigators may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to clinical trials that we may design on our own. Negative results in investigator-sponsored clinical trials could have a material adverse effect on our efforts to obtain regulatory approval for our product candidates and the public perception of our product candidates. As a result, our lack of control over the conduct and timing of and communications with the FDA and other regulatory authorities regarding investigator-sponsored trials may expose us to additional risks and uncertainties, many of which are outside our control, and the occurrence of which could adversely affect the commercial prospects for our product candidates. In addition, third parties that are investigating product candidates which have not been provided by us may seek and obtain regulatory approval of product candidates before we do, which may adversely affect our development strategy and eligibility for certain exclusivities for which we may otherwise be eligible.

We have completed and may in the future complete related party transactions that were not and may not be conducted on an arm's length basis.

We have in the past been and continue to be party to certain transactions with certain entities affiliated with Estuardo Aguilar-Cordova, our founder and former Chief Scientific Officer, and Laura Aguilar, our former Chief Medical Officer. For instance, we have entered into an exclusive license agreement with Ventagen, LLC (Ventagen), an entity owned in part (49.5%), though not managed, by Estuardo Aguilar-Cordova and Laura Aguilar, for the use of worldwide patent rights and know-how owned or controlled by us which cover applicable technology utilizing the delivery method of the herpes derived TK protein to tumors or other tissues via a viral vector.

In January 2008, we entered into an operating lease agreement with a term through December 31, 2022 with Ellka Holdings, LLC (Ellka), for the space in which we operated in Auburndale, MA. In May 2016, we entered into a second lease agreement with Ellka for living space for employees, also in Auburndale, MA. We entered into a second lease for this space on July 26, 2018, which expired on July 31, 2019. Ellka was originally established in 2007 as an LLC for the purpose of acquiring and managing investment properties owned by Laura Aguilar and Estuardo Aguilar-Cordova and their children's trusts. Ellka is owned and operated by Laura Aguilar and Estuardo Aguilar-Cordova and members of their immediate family. Although we

believe that these transactions were conducted on an arm's length basis, it is possible that the terms were less favorable to us than they might have been in a transaction with an unrelated party.

As of May 6, 2024, Estuardo Aguilar-Cordova and Laura Aguilar beneficially owned 6,200,755 shares of our common stock, or approximately 20.8% of our total outstanding capital stock as of such date. Accordingly, they will continue to have significant influence over all business decisions, including with respect to such matters as amendments to our charter, other fundamental corporate transactions, such as mergers, asset sales, and the sale of the Company, and otherwise will be able to influence our business and affairs. In connection with the IPO, we adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of related-person transactions.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture our product candidates, and because we collaborate with various organizations and academic institutions on the development of our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets.

Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks Related to Intellectual Property

Our rights to develop and commercialize certain of our product candidates are subject and may in the future be subject, in part, to the terms and conditions of licenses granted to us by third parties. If we fail to comply with our obligations under our current or future intellectual property license agreements or otherwise experience disruptions to our business relationships with our current or any future licensors, we could lose intellectual property rights that are important to our business.

We are and expect to continue to be reliant upon third-party licensors for certain patent and other intellectual property rights that are important or necessary to the development of some of our technology and product candidates. For example, we rely on licenses from MGB and Periphagen to certain patent rights. These license agreements impose, and we expect that any future license agreement will impose, specified diligence, milestone payment, royalty, commercialization, development and other obligations on us and require us to meet development timelines, or to exercise diligent or commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses.

Furthermore, our licensors have, or may in the future have, the right to terminate a license if we materially breach the agreement and fail to cure such breach within a specified period or in the event we undergo certain bankruptcy events. In spite of our best efforts, our current or any future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements. If any of our license agreements are terminated, we may lose our rights to develop and commercialize certain of our product candidates and technology, lose patent protection, experience significant delays in the development and commercialization of certain of our product candidates and technology, and incur liability for damages. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, our competitors or other third parties could have the freedom to seek regulatory approval of, and to market, products and technologies identical or competitive to ours and we may be required to cease our development and commercialization of certain of our product candidates and technology. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with any product candidates we may develop and our technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our or our licensors' ability to obtain, maintain and defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, product candidates and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other intellectual property rights under our license agreements;
- our diligence, development, regulatory, commercialization, financial or other obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, our license agreements are, and future license agreements are likely to be, 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 diligence, development, regulatory, commercialization, financial or other obligations under the relevant agreement. In addition, if disputes over intellectual property that we have licensed or any other dispute related to our license agreements prevent or impair our ability to maintain our current license agreements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and technology. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

License agreements we may enter into in the future may be non-exclusive. Accordingly, third parties may also obtain non-exclusive licenses from such licensors with respect to the intellectual property licensed to us under such license agreements. Accordingly, these license agreements may not provide us with exclusive rights to use such licensed patent and other intellectual property rights, or may not provide us with exclusive rights to use such patent and other intellectual property rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and any product candidates we may develop in the future.

Moreover, some of our in-licensed patent and other intellectual property rights may in the future be subject to third-party interests such as co-ownership. If we are unable to obtain an exclusive license to such third-party co-owners' interest, in such patent and other intellectual property rights, such third-party co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We or our licensors may need the cooperation of any such co-owners of our licensed patent and other intellectual property rights in order to enforce them against third parties, and such cooperation may not be provided to us or our licensors.

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

Furthermore, our owned and in-licensed patent rights may be subject to a reservation of rights by one or more third parties. When new technologies are developed with government funding, in order to secure ownership of patent rights related to the technologies, the recipient of such funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. A failure to meet these obligations may lead to a loss of rights or the unenforceability of relevant patents or patent applications.

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our business will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent

upon the extent to which we have rights under valid and enforceable patents that cover these activities and whether a court would issue an injunctive remedy. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue, obtain, or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees.

The strength of patents in the biotechnology and biopharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our technology, including our product candidates, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications and patents we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

We cannot be certain that we were the first to file any patent application related to our technology and directed to our product candidates, and, if we were not, we may be precluded from obtaining patent protection for our technology, including our product candidates.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and patents, and, if we are not, we may be subject to priority disputes. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. Similarly, for United States applications in which at least one claim is not entitled to a priority date before March 16, 2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor's disclosure.

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 or patent application 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. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, would adequately protect our product candidates, or would be found by a court to be infringed by a competitor's technology or product. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that may issue that cover our products.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of the patents we in-license or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law is more restrictive than U.S. patent law in connection with the patentability of methods of treatment of the human body and Chinese bankruptcy law may not provide a licensee the same protections as U.S. bankruptcy law.

Furthermore, in the United States, patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the Leahy-Smith America Invents Act (the America Invents Act), enacted in 2013, the United States moved from a "first to invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are unclear as the USPTO continues to develop new regulations and procedures in connection with the America Invents Act. In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are

particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could increase the uncertainties and costs surrounding the prosecution of our patent applications and have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

In addition, the European Union opened a Unified Patent Court (UPC) in June 2023. The UPC is a common patent court that hears patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of our European patents. We have opted out of the UPC for our European patents and applications and may decide to opt out of any future European patents and patent applications from the UPC. If certain formalities and requirements are not met, however, our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, even if we elected, or in the future elect, to opt out of the UPC.

We cannot predict whether the patent applications we in-license currently being pursued will issue as patents, whether the claims of any patent that has or may issue will provide us with a competitive advantage or prevent competitors from designing around the claims to develop competing technologies in a non-infringing manner, or whether we or our licensors will be able to successfully pursue patent applications in the future relating to our current product candidates or future products and product candidates. Moreover, the patent application and approval process is expensive and time-consuming. We or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Furthermore, we, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to seek additional patent protection.

Even if the patent applications we in-license issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patent rights by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our product candidates. Alternatively, our competitors may seek to market generic versions of any approved products by submitting abbreviated BLAs to the FDA during which process they may claim that patents licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our intellectual property rights, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find the patents we in-license invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have in-licensed valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the compositions of our product candidates but that are not covered by the claims of our patents or those of our licensors;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;

•the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;

•the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;

•our owned, co-owned, or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;

•the inventors of our owned, co-owned, or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;

•the co-owners of certain of our patent applications may become involved with, or license or assign the co-owned applications to competitors, or become hostile to us or the patents or patent applications on which they are named as co-owners;

•it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;

•we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;

•we may not develop additional proprietary technologies for which we can obtain patent protection;

•it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or

•the patents of others may have an adverse effect on our business.

We may enter into license or other collaboration agreements in the future that may impose certain obligations on us. If we fail to comply with our obligations under such future agreements with third parties, we could lose license rights that may be important to our future business.

In connection with our efforts to expand our pipeline of product candidates, we may enter into certain licenses or other collaboration agreements in the future pertaining to the in-license of rights to additional candidates. Such agreements may impose various diligence, milestone payment, royalty, insurance or other obligations on us. If we fail to comply with these obligations, our licensor or collaboration partners may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licensed intellectual property.

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

•the scope of rights granted under the license agreement and other interpretation-related issues;

•the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

•the sublicensing of patent and other rights under our collaborative development relationships;

•our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

•the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and

•the priority of invention of patented technology.

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

In addition, we may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, or any other intellectual property that may be related to our in-licensed intellectual property. For example, we

cannot be certain that such activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

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

In addition to patent protection, we rely upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third-party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. For example, our research development strategy includes the establishment of coculture cancer cells, immune cells and viruses. Our techniques for establishing these cocultures and testing our experimental agents in these assays are proprietary and confidential. If one or more third parties obtain or are otherwise able to replicate these techniques, an important feature and differentiator of our research development strategy will become available to potential competitors. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post-grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

•infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

•substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third-party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

•a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights to us, which it is not required to do;

•if a license is available from a third-party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products and any license that is available may be non-exclusive, which could result in our competitors gaining access to the same intellectual property; and

•redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. 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.

Our collaborators may assert ownership or commercial rights to inventions they develop from research we support or that we develop from our use of the tissue samples or other biological materials, which they provide to us, or otherwise arising from the collaboration.

We collaborate with several institutions, universities, medical centers, physicians and researchers in scientific matters and expect to continue to enter into additional collaboration agreements. In certain cases, we do not have written agreements with these collaborators, or the written agreements we have do not cover intellectual property rights. Also, we rely on numerous third parties to provide us with tissue samples and biological materials that we use to conduct our research activities and develop our product candidates. If we cannot successfully negotiate sufficient ownership and commercial rights to any inventions that result from our use of a third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's samples, or data developed in a collaborator's study, we may be limited in our ability to capitalize on the market potential of these inventions or developments.

Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents of which we are currently unaware with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment that encompass the composition, use or manufacture of our product candidates. There may be currently pending patent applications of which we are currently unaware which may later result in issued patents that our product candidates or their use or manufacture may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patent were held by a court of competent jurisdiction to cover our product candidates, intermediates used in the manufacture of our product candidates or our materials generally, aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize 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. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information, misappropriated trade secrets, or are in breach of non-competition or non-solicitation agreements with our competitors.

As is common in the biotechnology and biopharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. We may also be subject to claims that we caused an employee to breach the terms of their non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor or other party. 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. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources.

Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may 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 proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing our compounds and pre-existing biopharmaceutical compounds. 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 or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. 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 develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our current or future licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other

party from using the technology at issue on the grounds that our patents do not cover the technology in question or for other reasons. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. 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 may choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-examination, *inter partes* review or post-grant review proceeding. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the European Patent Office (EPO), or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference or derivation proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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 during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In certain circumstances, even inadvertent noncompliance events may permanently and irrevocably jeopardize patent rights. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO or could expire before the first product achieves marketing approval.

If we or one of our licensors initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third-party can assert invalidity or unenforceability of a patent.

Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Likewise, we own a U.S. patent relating to our CAN-2409 product candidate that expires in 2034, and our in-licensed U.S. and non-U.S. patents relating to our HSV-based product candidates, licensed from MGB and from Periphagen are expected to expire in 2036 and in 2037, respectively, without taking into account any possible patent term extensions. Our earliest patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. We own and in-license pending patent applications relating to our proprietary technologies or our product candidates that if issued as patents are expected to expire from 2034 through 2044, without taking into account any possible patent term adjustments or extensions. However, we cannot be assured that the USPTO or relevant foreign patent offices will grant any of these patent applications or that the term of the patent will be sufficient to protect the proprietary technologies or product candidates.

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

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and 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 where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of, and may require a compulsory license to, patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. 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 at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or 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 owned and licensed 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 and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the 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 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 business, financial condition, results of operations, and prospects could be materially harmed.

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

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 or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Risks Related to Our Common Stock

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

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

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- commencement or termination of collaboration, licensing or similar arrangements for our development programs;
- announcements by our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- developments or setbacks related to drugs that are co-administered with any of our product candidates, such as checkpoint inhibitors;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- expiration of market stand-off or lock-up agreements;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions and overall fluctuations in the financial markets in the United States and abroad; and
- the other factors described in this “Risk Factors” section.

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.

Our common stock is currently listed for trading on The Nasdaq Global Market (Nasdaq). We must satisfy the continued listing requirements of Nasdaq to maintain the listing of our common stock on Nasdaq. On November 15, 2023, we received a letter from the Listing Qualifications Department (the Staff) of The Nasdaq Stock Market LLC notifying us that, for the previous 30 consecutive business days, the closing bid price for our common stock had been below the minimum $1.00 per share required for continued listing on Nasdaq under Nasdaq Listing Rule 5450(a)(1) (the Bid Price Requirement). On December 28, 2023, the Staff notified us that, as of December 28, 2023, we had regained compliance with the Bid Price Requirement and that the matter was closed.

If we are deficient in maintaining the necessary listing requirements, our common stock may be delisted. If our common stock is delisted, an active trading market for our common stock may not be sustained and the market price of our common stock could decline. Delisting of our common stock could adversely affect our ability to raise additional capital through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

Raising additional capital through the sale of a substantial number of shares of our common stock, or the perception that sales of a substantial number of shares of our common stock might occur, may cause dilution to our stockholders, could cause our stock price to decline and could restrict our operations or require us to relinquish rights to our technologies or current or future product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that may materially adversely affect your rights as a common stockholder. In August 2022, we filed a registration statement on Form S-3 (as amended, the Shelf) pursuant to which we may issue up to $75.0 million in shares of common stock in sales deemed to be "at-the-market offerings" (the ATM Program) as defined by the Securities Act of 1933, as amended (Securities Act), and up to $200.0 million in shares of our common stock, preferred stock, debt securities, warrants and/or units. As of May 6, 2024, we have sold and issued 109,485 shares of common stock under the ATM Program, with total net proceeds of $0.2 million. Any sale or issuance of securities pursuant to this registration statement or otherwise may result in dilution to our stockholders and may cause our stock price to decline. During the three months ended March 31, 2024, we were subject to the SEC's "baby shelf rules," which prohibit companies with a public float of less than $75.0 million from issuing securities under a shelf registration statement in excess of one third of such company's public float in a 12-month period, and we were only able to issue a limited number of shares which aggregate to no more than one-third of our public float using our Shelf. On April 4, 2024, our public float increased above $75.0 million, and as a result, we are no longer subject to the "baby shelf rules." If our public float is less than $75.0 million on the applicable measurement date in the future, we will again become subject to the baby shelf rules. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms.

Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, acquiring, selling or licensing intellectual property rights, making capital expenditures, declaring dividends, or other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to meet certain milestones in connection with debt financing and the failure to achieve such milestones by certain dates may force us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us which could have a material adverse effect on our business, operating results and prospects.

If we raise funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or current or future product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, scale back or discontinue the development and commercialization of one or more of our product candidates, delay our pursuit of potential in-licenses or acquisitions or grant rights to develop and market current or future product candidates that we would otherwise prefer to develop and market ourselves.

We are an "emerging growth company" as defined in the JOBS Act and a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended (the Exchange Act), and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) December 31, 2026; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the SOX Act (Section 404);
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- providing only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. For example, we have taken advantage of reduced reporting burdens in our Annual Report on Form 10-K. In particular, we provided only two years of audited financial statements and a correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure, and did not include all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we no longer qualify an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

Although we are still evaluating the JOBS Act, we currently intend to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an “emerging growth company” and “smaller reporting company.” We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies or smaller reporting company. As a result, changes in rules of U.S. GAAP or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations. In addition, our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an “emerging growth company,” which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as a “smaller reporting company” or an “emerging growth company,” we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline.

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

As a public company, and particularly after we are no longer an “emerging growth company,” we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the SOX Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act), was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. Emerging growth companies may implement many of these requirements over a longer period and up to five years from the pricing of an initial public offering. We intend to take advantage of these extended transition periods but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to maintain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In additional, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

If our existing stockholders 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. As of May 6, 2024, we had a total of 29,744,731 shares of common stock outstanding.

In addition, shares of common stock that are reserved for future issuance under our 2021 Plan and our 2021 Employee Stock Purchase Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Certain holders of shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in such shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude

us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our executive officers, directors, principal stockholders and their affiliates exercise significant influence over our company, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

The existing holdings of our executive officers, directors, principal stockholders and their affiliates represent beneficial ownership, in the aggregate, of approximately 60.4% of our outstanding common stock with Estuardo Aguilar-Cordova and Laura Aguilar (together, both directly and indirectly) beneficially owning approximately 20.8% of our outstanding common stock, and with entities and persons affiliated with PBM Capital Group, LLC (PBM Capital), beneficially owning approximately 28.7% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, or the Delaware Forum Provision. The Delaware Forum Provision does not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, as our principal office is located in Needham, Massachusetts. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

We may be subject to securities litigation, which is expensive and could divert management's attention.

The market price of our common stock may be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In particular, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies were highly volatile as a result of the COVID-19 pandemic and may be volatile as a result of a similar public health crisis in the future. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

The number of shares of our common stock outstanding may increase substantially as a result of our November 2018 issuance of warrants to purchase up to an aggregate of 7,344,968 shares of common stock.

In connection with the November 13, 2018 issuance of Series B convertible preferred stock (the Series B Preferred), we issued to the purchaser of the Series B Preferred, warrants to purchase 3,672,484 shares of common stock for $6.81 per share (the Series B Warrants) which were and remain fully exercisable upon issuance. The Series B Warrants contain provisions allowing cashless exercise.

In addition, we issued to the same stockholder additional five-year warrants for the purchase of 3,672,484 shares of common stock for $6.81 per share (the Conditional Series B Warrants), which become exercisable in the event that we complete a future financing that meets certain financial milestones or achieves certain share prices as follows:

•918,121 shares vest upon (1) a financing event effected through the sale of our equity securities to third parties resulting in at least $20,000,000 in gross proceeds with a per share price of $12.47, or (2) an average market price (determined over a consecutive 10-day period) of $12.47 per share;

•an additional 918,121 shares vest upon (1) a financing event with a price per share of $13.20, or (2) an average market price (determined over a consecutive 10-day period) of, $13.20 per share;

•an additional 918,121 shares vest upon (1) a financing event with a per share price of $13.94, or (2) an average market price (determined over a consecutive 10-day period) of, $13.94 per share; and

•an additional 918,121 shares vest upon (1) a financing event with a per share price of $14.68, or (2) an average market price (determined over a consecutive 10-day period) of, $14.68 per share.

On June 24, 2021, our board of directors approved, and on July 14, 2021, our stockholders approved, effective upon the closing of the IPO, an amendment to the terms of the Series B Warrants and the Conditional Series B Warrants to extend the expiration date from November 2023 to November 2025. In addition, the exercise period for the Conditional Series B Warrants was amended such that in the event the future financing milestones or certain share price targets described above are achieved, the Conditional Series B Warrants can only be exercised in conjunction with the sale of the company, on a cash or cashless exercise basis, or otherwise in November 2025 through a cashless exercise.

We recorded the Series B Warrants as a component of stockholder's equity at the time of issuance at their estimated fair value of $2.1 million and recorded the Conditional Series B Warrants as a liability on the condensed consolidated balance sheet because the number of shares used to calculate the settlement is not a fixed number of shares. The Conditional Series B Warrants are remeasured to their fair value at each reporting date with changes in the fair value recognized as a component of other income (expense), net in the condensed consolidated statements of operations. We will continue to recognize changes in the fair value of the Conditional Series B Warrants until each Conditional Series B Warrant is exercised, expires or qualifies for equity classification.

The exercise of these warrants in full, assuming vesting in full of the Conditional Series B Warrants and no net exercise, would result in an additional 7,344,968 shares of common stock outstanding, resulting in substantial dilution to stockholders who hold our common stock. In addition, if the holders of these warrants, including PBM Capital, were to exercise such warrants in full, these holders could then have significant influence over the outcome of any stockholder vote, including the election of directors and the approval of mergers or other business combination transactions.

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

(a) Recent Sales of Unregistered Equity Securities

None.

(b) Use of Proceeds from the Initial Public Offering of Common Stock

The offer and sale of all the shares of our common stock in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (Reg. No. 333-257444), as amended, which was declared effective by the SEC on July 26, 2021. There has been no material change in the expected use of the net proceeds from our Annual Report on Form 10-K for the year ended December 31, 2023 as filed with the SEC on March 28, 2024.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the three months ended March 31, 2024, none of our directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended) adopted, terminated or modified a Rule 10b5-1 trading arrangement or any “non-Rule 10b5-1 trading agreement” (as defined in Item 408(c) of Regulation S-K).

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Candel Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on July 30, 2021)
3.2	Amended and Restated Bylaws of Candel Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on July 30, 2021)
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333- 257444) filed with the SEC on July 16, 2021)
10.1	Consulting Agreement by and between Candel Therapeutics, Inc. and Jason A. Amello, dated as of January 12, 2024 (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 28, 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.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*+	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*+	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

+ The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to be furnished with this Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

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.

Candel Therapeutics, Inc.

Date: May 14, 2024 By: /s/ Paul Peter Tak
Paul Peter Tak
President and Chief Executive Officer

Date: May 14, 2024 By: /s/ Charles Schoch
Charles Schoch
Interim Chief Financial Officer
(Principal financial officer and principal accounting officer)

Exhibit 31.1

CERTIFICATIONS

I, Paul Peter Tak, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Candel 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/ Paul Peter Tak

Paul Peter Tak

President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS

I, Charles Schoch, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Candel 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/ Charles Schoch

Charles Schoch

Interim Chief Financial Officer
(principal financial officer and principal 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 of Candel Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul Peter Tak, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Date: May 14, 2024

By: /s/ Paul Peter Tak

Paul Peter Tak
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 of Candel Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Charles Schoch, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Date: May 14, 2024

By: /s/ Charles Schoch

Charles Schoch
Interim Chief Financial Officer
(principal financial officer and principal accounting officer)