UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

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 July 31, 2022, the registrant had 28,891,909 shares of common stock, $0.01 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or 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 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 effect of the ongoing COVID-19 pandemic, 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; and
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- 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 ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in Part II, Item 1A - Risk Factors in this Form 10-Q. These risks include, among others:

- 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. Our net loss was $5.0 million and $21.6 million for the six months ended June 30, 2022 and 2021, respectively.
- We will need to raise substantial additional funding. 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.
- Our business is dependent on the success of our lead 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.
- 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-initiated 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.
- The ongoing COVID-19 pandemic, which began in late 2019 and has spread worldwide, 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, the ongoing COVID-19 pandemic has caused 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.
- 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 quarterly report on 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 quarterly report on 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)
(Unaudited)

	JUNE 30, 2022	DECEMBER 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 86,782	$ 82,642
Prepaid expenses and other current assets	544	2,303
Total current assets	87,326	84,945
Fixed assets, net	4,545	3,836
Lease right of use assets	1,164	—
Restricted cash	266	424
Total assets	$ 93,301	$ 89,205
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,584	$ 1,590
Accrued expenses	3,791	3,438
Current portion of lease liability	440	—
Other current liabilities	63	334
Total current liabilities	5,878	5,362
Deferred rent	—	894
Term loan payable to a bank	20,026	—
Other long-term debt	604	560
Lease liability, net of current portion	1,725	—
Warrant liability	4,996	18,252
Total liabilities	33,229	25,068
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 10,000,000 shares authorized at June 30, 2022 and December 31, 2021, no shares issued or outstanding at June 30, 2022 and December 31, 2021, respectively.	—	—
Common stock, $0.01 par value; 150,000,000 shares authorized at June 30, 2022 and December 31, 2021; 29,014,517 and 28,689,842 shares issued at June 30, 2022 and December 31, 2021, respectively; 28,891,909 and 28,689,842 shares outstanding at June 30, 2022 and December 31, 2021, respectively.	290	286
Additional paid-in capital	145,548	144,146
Treasury stock (at cost)	(448)	—
Accumulated deficit	(85,318)	(80,295)
Total stockholders' equity	60,072	64,137
Total liabilities and stockholders' equity	$ 93,301	$ 89,205

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

CANDEL THERAPEUTICS, INC.

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

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2022	2021	2022	2021
Research and development service revenue, related party	$ 31	$ 31	$ 63	$ 63
Operating expenses:				
Research and development	5,022	3,292	10,438	6,048
General and administrative	3,762	2,040	7,364	3,972
Total operating expenses	8,784	5,332	17,802	10,020
Loss from operations	(8,753)	(5,301)	(17,739)	(9,957)
Other income (expense):				
Grant income	—	605	—	796
Interest, dividend and investment income (expense), net	(365)	(15)	(540)	(28)
Change in fair value of warrant liability	4,969	(12,369)	13,256	(12,369)
Total other income (expense), net	4,604	(11,779)	12,716	(11,601)
Net loss	$ (4,149)	$ (17,080)	$ (5,023)	$ (21,558)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.14)	$ (1.46)	$ (0.17)	$ (1.85)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	28,810,224	11,720,530	28,750,431	11,684,374

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 and per share amounts)
(Unaudited)

	COMMON STOCK		TREASURY STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	STOCKHOLDERS' EQUITY
	SHARES	AMOUNT	SHARES	AMOUNT			
Balance, December 31, 2021	28,689,842	$ 286	—	$ -	$ 144,146	$ (80,295)	$ 64,137
Options exercised	324,675	4	—	—	472	—	476
Treasury stock acquired	—	—	(122,608)	(448)	0	—	(448)
Stock-based compensation	—	—	—	—	1,552	—	1,552
Change in fair value of NC Ohio Trust Warrants	—	—	—	—	(622)	—	(622)
Net loss	—	—	—	—	—	(5,023)	(5,023)
Balance, June 30, 2022	29,014,517	$ 290	(122,608)	$ (448)	$ 145,548	$ (85,318)	$ 60,072

	COMMON STOCK		TREASURY STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	STOCKHOLDERS' EQUITY
	SHARES	AMOUNT	SHARES	AMOUNT			
Balance, March 31, 2022	28,693,151	$ 287	—	$ -	$ 144,644	$ (81,169)	$ 63,762
Options exercised	321,366	3	—	—	467	—	470
Treasury stock acquired	—	—	(122,608)	(448)	—	—	(448)
Stock-based compensation	—	—	—	—	724	—	724
Change in fair value of NC Ohio Trust Warrants	—	—	—	—	(287)	—	(287)
Net loss	—	—	—	—	—	(4,149)	(4,149)
Balance, June 30, 2022	29,014,517	$ 290	(122,608)	$ (448)	$ 145,548	$ (85,318)	$ 60,072

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

CANDEL THERAPEUTICS, INC.

Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands, except share and per share amounts)
(unaudited)

	SERIES B CONVERTIBLE PREFERRED STOCK		SERIES C CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	STOCKHOLDERS' EQUITY (DEFICIT)
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT			
Balance, December 31, 2020	11,155,506	$ 26,560	6,032,170	$ 22,500	11,635,094	$ 116	$ 20,493	$ (44,171)	$ (23,562)
Options exercised	—	—	—	—	24,410	—	35	—	35
Warrants exercised	—	—	—	—	72,385	1	409	—	410
Stock-based compensation	—	—	—	—	—	—	1,250	—	1,250
Change in fair value of NC Ohio Trust Warrants	—	—	—	—	—	—	250	—	250
Net loss	—	—	—	—	—	—	—	(21,558)	(21,558)
Balance, June 30, 2021	11,155,506	$ 26,560	6,032,170	$ 22,500	11,731,889	$ 117	$ 22,437	$ (65,729)	$ (43,175)

	SERIES B CONVERTIBLE PREFERRED STOCK		SERIES C CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	STOCKHOLDERS' EQUITY (DEFICIT)
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT			
Balance, March 31, 2021	11,155,506	$ 26,560	6,032,170	$ 22,500	11,673,135	$ 117	$ 21,035	$ (48,649)	$ (27,497)
Options exercised	—	—	—	—	58,754	—	333	—	333
Stock-based compensation	—	—	—	—	—	—	819	—	819
Change in fair value of NC Ohio Trust Warrants	—	—	—	—	—	—	250	—	250
Net loss	—	—	—	—	—	—	—	(17,080)	(17,080)
Balance, June 30, 2021	11,155,506	$ 26,560	6,032,170	$ 22,500	11,731,889	$ 117	$ 22,437	$ (65,729)	$ (43,175)

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

CANDEL THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows
(In thousands, except share and per share amounts)
(Unaudited)

	SIX MONTHS ENDED JUNE 30,	
	2022	**2021**
Cash Flows from Operating Activities:		
Net loss	$ (5,023)	$ (21,558)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	352	33
Non-cash stock compensation expense	930	1,500
Non-cash lease expense	101	—
Non-cash interest expense	44	39
Change in fair value of warrant liability	(13,256)	12,369
Accretion of debt discount	115	—
Paycheck protection program loan forgiveness	—	(464)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,760	(18)
Accounts payable	(161)	(177)
Accrued expenses	276	(1,228)
Deferred revenue	(63)	(63)
Deferred rent	—	(13)
Lease liability	(225)	—
Other long term assets	—	(506)
Net cash used in operating activities	**(15,150)**	**(10,086)**
Cash Flows from Investing Activities:		
Purchase of fixed assets	(806)	(939)
Net cash used in investing activities	**(806)**	**(939)**
Cash Flows from Financing Activities:		
Net proceeds from bank term loan	19,910	—
Proceeds from option exercises	28	35
Proceeds from warrant exercises	—	410
Net cash provided by financing activities	**19,938**	**445**
Net increase (decrease) in cash	**3,982**	**(10,580)**
Cash, cash equivalents and restricted cash at beginning of period	**83,066**	**35,319**
Cash, cash equivalents and restricted cash at end of period	**$ 87,048**	**$ 24,739**
Supplemental cash flow information:		
Cash paid for taxes	$ 133	$ 21
Cash paid for interest	$ 328	$ -
Supplemental disclosures of non-cash information:		
Lease liability arising from obtaining right-of-use assets	$ 2,368	$ -
Capital expenditures in accounts payable and accrued expenses	$ 254	$ 1,612
Common stock exchange for option exercise	$ 448	$ -

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 late clinical stage biotechnology 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 helping patients fight cancer with oncolytic viral immunotherapies. 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. The Company has established two oncolytic viral immunotherapy platforms and its two product candidates, CAN-2409 and CAN-3110, are in clinical trials for a number of tumor types.

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.

The Company has funded its operations primarily with proceeds from the sale of its capital stock and convertible notes. The Company has incurred recurring losses since its inception, including a net loss of $5.0 million and $21.6 million for the six months ended June 30, 2022 and 2021, respectively. In addition, as of June 30, 2022, the Company had an accumulated deficit of $85.3 million. The Company expects to continue to generate operating losses for the foreseeable future. On July 29, 2021, the Company completed its initial public offering of common stock, or the IPO, at which time the Company issued 9,000,000 shares of its common stock at a price to the public of $8.00 per share, and on August 13, 2021, the Company issued an additional 887,994 shares of common stock at $8.00 per share as a partial exercise of the underwriters’ option to purchase additional shares, resulting in net proceeds to the Company of $71,335, after deducting underwriting discounts and commissions and offering expenses. Upon closing of the IPO, all outstanding shares of the Company’s convertible preferred stock automatically converted into 7,066,398 shares of common stock.

The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company’s inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurances that additional funding will be available on terms acceptable to the Company, or at all. The Company believes that existing resources will fund planned operations for at least 12 months from the date that these condensed consolidated financial statements were available to be issued.

Accordingly, the condensed consolidated financial statements have been prepared on a basis that assumes the Company continue as a going concern and 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 Financial Accounting Standards Board ("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 *Accounting Standards* Codification ("ASC").

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 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 June 30, 2022, the condensed consolidated statements of operations for the three and six months ended June 30, 2022 and 2021, the condensed consolidated statements of stockholders' equity (deficit) for the three and six months ended June 30, 2022 and 2021, the condensed consolidated statements of cash flows for the six months ended June 30, 2022 and 2021, and the related interim disclosures are unaudited. These unaudited 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, 2021 included in the Company's Annual Report on Form 10-K ("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.

Prior to the IPO, the Company utilized significant estimates and assumptions in determining the fair value of its common stock. The Company has utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation (the "Practice Aid"), to estimate the fair value of its common stock and warrants. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with original final maturities of 90 days or less from the date of purchase to be cash equivalents. Cash and cash equivalents comprise marketable securities with maturities of less than 90 days when purchased. Cash equivalents are reported at fair value.

Restricted cash

The Company has $266 and $424 of restricted cash as of June 30, 2022 and December 31, 2021, respectively, which represents cash held in a restricted bank account under the terms of the Company's Needham, Massachusetts facility lease and at December 31, 2021, as security for the Company credit card.

Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial

assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of cash and cash equivalents, accounts payable, and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. The Company's warrant liability is carried at fair value and is classified as Level 3 measurement.

Property and equipment

Property and equipment consist of lab and manufacturing equipment, networking and computer equipment, furniture and fixtures and leasehold improvements. Property and equipment are recorded at cost, and depreciated using the straight-line method over the estimated useful lives of the respective assets:

ASSET	ESTIMATED USEFUL LIFE
Networking and computer equipment	5 years
Laboratory equipment	5 years
Manufacturing equipment	5 years
Furniture and fixtures	5 years
Leasehold improvements	Shorter of the useful life or remaining lease term

Leases

The Company adopted ASC 842 as of January 1, 2022 and elected the transition method under ASU 2016-02 whereby the Company records a right-of-use asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. The Company also elected to apply the practical expedients intended to ease transition. Accordingly, the Company has only applied ASC 842 to leases existing as of January 1, 2022. The Company determines if an arrangement is, or contains, a lease at inception.

Lease right of use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Lease right of use assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments to be made over the lease term. The lease right of use asset is equal to the lease liability and adjusted for prepaid rent, initial direct costs, and incentives. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term. The Company has elected to not apply the recognition requirements of ASC 842 for short-term leases, which is defined as a lease that, at the lease commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the Company is reasonably certain to exercise.

For real estate lease agreements entered into or modified after the adoption of ASC 842 that include lease and non-lease components, the Company has elected to account for the lease and non-lease components, such as common area maintenance charges, as a single lease component term.

Concentrations of credit risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. Periodically, the Company maintains deposits and investments in accredited financial institutions in-excess of the federally insured limits. The Company deposits its cash in financial institutions with a high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal risk associated with commercial banking relationships.

Impairment of long-lived assets

Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations,

significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. Long-lived assets consist of fixed assets and operating lease assets.

In the fourth quarter of 2021, the Company recorded an impairment charge of approximately $553 related to manufacturing equipment that the Company does not plan to use for its intended use and recorded a reserve to reduce the carrying value to its estimated realizable value. The Company has not recorded any additional impairment losses on such long-lived assets.

Revenue recognition

The Company applies Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, (ASC 606). This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and then assesses whether or not each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Research and development costs and accruals

Research and development expenses include salaries and benefits, materials and supplies, preclinical and clinical trial expenses, stock-based compensation expense, depreciation of equipment, contract services and other outside expenses. The Company has entered into various research and development-related contracts with clinical and research institutions, contract research organizations, and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. Costs of certain development activities, such as manufacturing, pre-clinical and clinical trial expenses, are recognized based on an evaluation of the progress to completion of specific tasks. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development costs. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. Costs incurred in obtaining technology licenses and intellectual property are charged to research and development expenses as acquired in-process research and development if the technology licensed or intellectual property acquired has not reached technological feasibility and has no alternative future use.

Patent costs

All patent-related costs incurred in connection with preparing, filing, maintaining and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified in general and administrative expenses.

Stock-based compensation

The Company accounts for its stock-based compensation in accordance with ASC Topic 718, *Compensation—Stock Compensation* (ASC 718). ASC 718 requires all share-based payments to employees and directors to be recognized as expense in the consolidated statements of operations based on their grant date fair values. In addition, in accordance with FASB Accounting Standards Update ("ASU") 2016-09 which identifies areas for simplification of several areas of share-based payment transactions, the Company treats non-employee grants the same as employee grants. The Company estimates the fair value of options granted using the Black-Scholes option pricing model for stock option grants to both employees and non-employees. The Company believes the fair value of the stock options granted to non-employees is more reliably determinable than the fair value of the services provided.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to a lack

of company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. For options granted to non-employees, the Company utilizes the contractual term of the share-based payment as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

Prior to the IPO, there were significant judgments and estimates inherent in the determination of the fair value of the Company's common stock. These estimates and assumptions included a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to its common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale.

The Company generally expenses the fair value of its share-based compensation awards to employees and non-employees on a straight-line basis over the requisite service period, which is generally the vesting period.

Government grants

The Company has applied for grants for the reimbursement of expenditures with the National Institutes of Health ("NIH") for certain qualified operating expenditures. The Company recognizes government grants when there is reasonable assurance that the Company will comply with the conditions attached to the grant arrangement and the grant will be received.

Government grants for research and development efforts are recorded as grant income and classified in other income in the statements of operations. The Company had no government grant revenue in 2022 and recognized government grant revenue of $605 and $796 for the three and six months ended June 30, 2021. Grant income is recognized as a component of other income/(expense), net in the condensed consolidated statements of operations. The Company's grant with the NIH was completed at the end of 2021.

Income taxes

The Company accounts for income taxes using the asset and liability method in accordance with ASC Topic 740, Income Taxes (ASC 740) which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies. At June 30, 2022 and December 31, 2021, the Company has concluded that a full valuation allowance is necessary for its deferred tax assets (see Note 12).

The Company accounts for uncertainty in income taxes by applying the two-step process to determine the amount of tax benefit to be recognized in the financial statements. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax is then assessed as the amount of benefits to be recognized in the consolidated financial statements. The amount of benefits that may be used are the largest amounts that have a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves or unrecognized tax benefits that are considered appropriate, as well as the related net interest and received.

Net loss per share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed using the weighted-average number of shares of common stock outstanding during the period and, if dilutive, the weighted-average number of potential shares of common stock. Diluted net loss per share is the same as basic net loss per share for the three and six months ended June 30, 2022 and 2021 since all potential shares of common stock instruments are anti-dilutive as a result of the loss for such periods.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods where the Company reports a net loss attributable to common stockholders, diluted net loss per share is the same as basic net loss per share, since dilutive shares of common stock are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the three and six months ended June 30, 2022 and 2021.

Recently adopted accounting standards

In February 2016, the FASB issued ASU 2016-02, Leases *(Topic 842) ("ASU 2016-02")*, as amended by various subsequently issued ASUs. The standard requires lessees to recognize an operating lease with a term greater than one year on their balance sheets as a right-of-use asset and corresponding lease liability, measured at the present value of the lease payments. Lessees are required to classify leases as either finance or operating leases. If the lease is effectively a financed purchase by the lessee, it is classified as a financing lease, otherwise it is classified as an operating lease. This classification will determine the pattern of recognition of lease cost on our condensed and consolidated statement of operations over the term of the lease.

In July 2018, the FASB also issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements ("ASU 2018-11")*, which permits entities to continue applying legacy guidance in ASC 840, Leases, including its disclosure requirements, in the comparative periods presented in the year that the entity adopts the new leasing standard. The Company elected the package of practical expedients permitted under the transition guidance within the standard. Accordingly, the Company did not reassess the conclusion of whether the existing arrangements contain a lease, lease classification and initial direct costs under ASC 842.

In June 2020, the FASB also issued ASU 2020-05, *Revenue from contracts with customers (Topic 606) and Leases (Topic 842): effective dates for certain entities,* which deferred the effective date certain entities were required to adopt ASC 842. The update extended the effective date for adoption of ASC 842 until fiscal years beginning after December 15, 2021. As an emerging growth company we were not required to adopt ASC 842 until January 1, 2022. The Company adopted the standard on January 1, 2022 using the effective date method. As such, the condensed consolidated balance sheets and statements of operations for prior periods will not be comparable in the year of adoption of ASC 842.

As a result of the adoption of ASC 842, the Company recorded a lease right of use asset of $1,264 and a lease liability of $2,368 on the condensed consolidated balance sheets as of January 1, 2022 related to an operating lease. The Company derecognized deferred rent liabilities, which makes up the difference between the lease right of use asset and lease liability. The adoption of the standard did not have a material impact on the Company's condensed consolidated statement of operations or condensed consolidated statement of cash flows.

In August 2020, the FASB issued ASU 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40*). The guidance simplifies the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. This ASU (1) simplifies the accounting for convertible debt instruments and convertible preferred stock by removing guidance in ASC 470-20, *Debt: Debt with Conversion and Other Options*, that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock; (2) revises the scope exception from derivative accounting in ASC 815-40 for freestanding financial instruments and embedded features that are both indexed to the issuers own stock and classified in stockholders' equity, by removing certain criteria required for equity classification; and (3) revises the guidance in ASC 260, *Earnings Per Share*, to require entities to calculate diluted earnings per share for convertible instruments by using the if-converted method. As an emerging growth company, we are not required to adopt ASU 2020-06 until January 1, 2024, however early adoption is permitted. The Company elected to early adopt the standard on January 1, 2022 and upon adoption, there was no impact to our condensed consolidated statement of operations and cash flows and our basic and diluted net loss per share amounts.

In November 2021, the FASB issued ASU 2021-10, which created Topic 832, Government Assistance, which requires business entities to disclose information about certain government assistance they receive. The ASU requires qualitative and quantitative disclosures around the nature of transactions and related accounting policy used, the line items on the balance sheet and income statement that are affected, and the significant terms and conditions of the transactions. The ASU is effective for fiscal years beginning after December 15, 2021. The Company believes its historical disclosure already met the requirements of the new standard. As such, no changes or additional disclosure was determined to be necessary.

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:

	FAIR VALUE MEASUREMENTS AS OF JUNE 30, 2022 USING:			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Liabilities:				
Warrant liability	—	—	4,996	4,996
Total	$ —	$ —	$ 4,996	$ 4,996

	FAIR VALUE MEASUREMENTS AS OF DECEMBER 31, 2021 USING:			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Liabilities:				
Warrant liability	—	—	18,252	18,252
Total	$ —	$ —	$ 18,252	$ 18,252

Valuation of warrant liability

In connection with the November 13, 2018 issuance of Series B convertible preferred stock, the Company issued warrants to purchase shares of common stock of which certain warrants are shown as a liability on the balance sheet, see Note 10. The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the warrant liability 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, expected volatility of the price of the underlying common stock, and the remaining contractual term of the warrants. The most significant assumption in the model impacting the fair value of the common stock warrants is the fair value of the Company's common stock as of each remeasurement date. Prior to the IPO, the Company determined the fair value per share of the underlying common stock by taking into consideration the most recent sales of preferred stock, results obtained from third-party valuations and additional factors that are deemed relevant.

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:

	SERIES B WARRANT LIABILITY
Balance at December 31, 2021	$ 18,252
Change in fair value	(13,256)
Balance at June 30, 2022	$ 4,996

4. Fixed assets, net

Fixed assets, net consisted of the following:

	JUNE 30, 2022	DECEMBER 31, 2021
Laboratory equipment	$ 1,037	$ 77
Manufacturing equipment	933	933
Furniture and fixtures	156	112
Networking and computer equipment	81	72
Leasehold improvements	3,042	2,994
Total fixed assets	$ 5,249	$ 4,188
Less: accumulated depreciation	(704)	(352)
Fixed assets, net	$ 4,545	$ 3,836

Depreciation and amortization expense for the three and six months ended June 30, 2022 was $187 and $352, respectively. Depreciation and amortization expense for the three and six months ended June 30, 2021 was $7 and $33, respectively.

5. Accrued expenses

Accrued expenses consisted of the following:

	JUNE 30, 2022	DECEMBER 31, 2021
Payroll and employee related expenses	$ 2,182	$ 2,096
Third-party research and development expenses	897	632
Professional fees and other	712	710
	$ 3,791	$ 3,438

6. Term Loan payable to a Bank

On February 24, 2022, the Company entered into a 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 can borrow up to an additional aggregate principal amount not to exceed $5.0 million, at any time on or prior to December 31, 2022, following the Company having provided evidence to SVB of (a) achievement of 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 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. 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 the three and six months ended June 30, 2022, the Company recorded interest expense relating to the Loan Agreement of $412 and $561, respectively. The weighted average effective interest rate as of June 30, 2022 was 8.17%.

The Company incurred $90 of debt issuance costs and will incur a $900 final payment fee, which were recorded as debt discount and are being amortized over the term of the Loan Agreement. See the table below for additional details;

	JUNE 30, 2022
Principal	$ 20,000
Final payment fee	900
Less: debt discount	(989)
Accretion of debt discount	115
Net carrying amount	$ 20,026

7. Other long-term debt

Periphagen Note

On December 9, 2019, the Company entered into a series of asset purchase agreements with Periphagen, Inc., a biopharmaceutical company focused on the development of gene therapy vectors. Under the terms of the asset purchase agreements, the Company assumed a $1,000 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%. 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 $417 at the transaction date. As of June 30, 2022, the present value of future cash flows outflows is $604.

8. Lease

On February 4, 2019, the Company signed a lease agreement for its new 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. Prior to occupying the new space, the Company had construction performed to modify the space to meet its needs. The cost of this construction was $765 and was paid for by the landlord provided allowance in the lease agreement. The $765 lease incentive was recorded as reduction to the lease right of use asset recorded to the Company's condensed consolidated balance sheet upon adoption of ASC 842 on January 1, 2022.

Disclosures under ASC 842

For the three and six months ended June 30, 2022, the Company has recorded $90 and $179, respectively of operating lease cost and for the three and six months ended June 30, 2022, the Company has recorded $44 and $92, respectively of variable lease cost. The total lease expense for the three and six months ended June 30, 2022 was $134 and $271, respectively.

Cash paid for amounts included in the lease liability for the three and six months ended June 30, 2022 was $141 and $281, respectively.

Other Information	JUNE 30, 2022
Operating cash flows used for operating leases	$ 281
Weighted-average remaining lease term	4.2
Weighted-average incremental borrowing rate	7.02%

The future lease payments under non-cancelable leases at June 30, 2022, are as follows:

2022	$ 286
2023	583
2024	598
2025	613
2026	415
Total future lease payments	2,496
Less: imputed interest	(331)
Total lease liability	$ 2,165

Disclosures under ASC 840

For the three and six months ended June 30, 2021, the Company recorded rent expense of $153 and $324, respectively.

The following table summarizes the future minimum lease payments due under the Company's facility lease as of December 31, 2021, presented in accordance with ASC 840, the relevant accounting standard at that time:

2022	$ 567
2023	583
2024	598
2025	613
2026	415
Total future lease payments	$ 2,776

9. Common stock and preferred stock

Preferred stock

The Company has authorized 10,000,000 shares of $0.01 par value preferred stock at June 30, 2022 and December 31, 2021.

Common stock

The Company has authorized 150,000,000 shares of $0.01 par value common stock at June 30, 2022 and December 31, 2021 of which 29,014,517 and 28,689,842 were issued as of June 30, 2022 and December 31, 2021, respectively. The Company had 28,891,909 and 28,689,842 outstanding shares as of June 30, 2022 and December 31, 2021, respectively. 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;

	JUNE 30, 2022	DECEMBER 31, 2021
Series B preferred conversion	—	—
Series C preferred conversion	—	—
Stock options outstanding	5,650,785	4,783,333
Shares available for future grant under stock option plan	1,854,464	1,878,997
Warrants	7,507,708	7,507,708
	15,012,957	14,170,038

Reverse stock split

On July 14, 2021, the Company's board of directors and stockholders approved a one-for-2.4579 reverse stock split of the Company's issued and outstanding common stock and a proportional adjustment to the existing conversion ratios for the outstanding shares of convertible preferred stock which became effective on July 15, 2021. Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

Initial public offering

The Company completed the IPO, including the partial exercise of the underwriters' option to purchase additional shares, at which time the Company issued 9,887,994 shares of its common stock at a price to the public of $8.00 per share, resulting in net proceeds to the Company of $71,335, after deducting underwriting discounts and commissions and offering expenses. Upon closing of the IPO, all outstanding shares of the Company's Preferred Stock automatically converted into 7,066,398 shares of common stock.

10. Warrants

The Company has the following warrants outstanding for the purchase of common stock as of June 30, 2022 and December 31, 2021:

WARRANT	SHARES OF COMMON STOCK SUBJECT TO WARRANTS	EXERCISE PRICE PER SHARE	EXPIRATION DATES
Series B Warrants	3,672,484	$ 6.81	November 2023
Series B Conditional Warrants	3,672,484	$ 6.81	November 2023
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 Company issued warrants to purchase 3,672,484 shares of common stock for $6.81 per share to the purchaser of the Series B preferred (the "Series B Warrants") which are exercisable upon issuance. In addition, the Company issued to the same stockholder additional five-year warrants for the purchase of 3,672,484 shares of common for $6.81 per share which are only exercisable in the event that the Company completes a future financing that meets certain financial milestones or achieves certain share prices (the "Conditional Series B Warrants"). The Series B Warrants and the Conditional Series B Warrants contain provisions allowing 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 $2,124 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. 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 $4,996 and $18,252 as of June 30, 2022 and December 31, 2021, respectively.

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 IPO, an amendment to the terms of the Series B Warrant and the Conditional Series B Warrants to extend the

expiration date from November 2023 to November 2025. In addition, the terms of the Conditional Series B Warrants were amended such that in the event the future financing milestones or certain share prices are achieved, the warrants would only be exercisable in conjunction with the sale of the Company or in November 2025 through a cashless exercise.

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 arrangement is unknown to the beneficiary as the arrangement is a silent trust. The Company recognizes the warrants as compensation expense within the condensed consolidated statement of operations and 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 June 30, 2022 and December 31, 2021, 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 $447 and $1,069 as of June 30, 2022 and December 31, 2021, respectively, 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

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 June 30, 2022, 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, or 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. There are 2,054,000 shares of common stock reserved for issuance under the 2021 Plan and 1,854,464 shares remained available for grants as of June 30, 2022. Stock option activity is summarized as follows:

	NUMBER OF STOCK OPTIONS	WEIGHTED-AVERAGE EXERCISE PRICE
Outstanding as of December 31, 2021	4,783,333	$ 2.34
Granted	1,222,400	4.23
Cancelled, forfeited or expired	(30,273)	4.19
Exercised	(324,675)	1.46
Outstanding as of June 30, 2022	5,650,785	$ 2.79
Exercisable as of June 30, 2022	2,410,505	$ 2.11
Unvested as of June 30, 2022	3,240,280	$ 3.30

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 and consolidated financial statements at June 30, 2022.

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

	SIX MONTHS ENDED JUNE 30,	
	2022	2021
Expected option life (years)	6.02 - 6.08	5.00 - 6.25
Risk-free interest rate	1.69% - 3.03%	0.89% - 1.12%
Expected volatility	85.09% - 86.09%	85.87% - 89.02%
Expected dividend yield	0%	0%
Exercise price	$3.24 - $5.19	$4.97 - $6.64
Fair value of common stock	$3.24 - $5.19	$4.97 - $6.64

The total intrinsic value of stock options vested during the six months ended June 30, 2022 and 2021 was $819 and $411, respectively.

Stock-based compensation expense for the three and six months ended June 30, 2022 and 2021 was classified in the condensed consolidated statements of operations as follows:

	THREE MONTHS ENDED June 30,		SIX MONTHS ENDED JUNE 30,	
	2022	2021	2022	2021
Research and development	$ 57	$ 400	$ 199	$ 516
General and administrative	381	669	730	984
Total stock-based compensation expense	$ 438	$ 1,069	$ 929	$ 1,500

As of June 30, 2022 and 2021, total unrecognized compensation cost related to the unvested stock-based awards was $7,332 and $6,060, respectively. As of June 30, 2022 and 2021, these amounts are expected to be recognized over a weighted average period of 2.45 and 2.73 years, respectively.

12. Income taxes

During the six months ended June 30, 2022 and 2021, the Company recorded a full valuation allowance on federal and state deferred tax assets since management does not forecast the Company to be in a profitable position in the near future.

13. 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 $1,000 upon the signing of the agreement and agreed to a fixed future payment to the Company of $2,500. The future payment will be made upon the achievement of $5,000 of sales of an approved product by Ventagen and is subject to reduction if Ventagen’s costs to develop an approved product exceeds $4,000. 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 is recognizing the $1,000 upfront license fee as research and development service revenue, related party, as the Company’s license agreement with Ventagen is within the scope of ASC 606. The license agreement met the contract existence criteria and contained distinct, identifiable performance obligations for which the stand-alone selling prices were readily determinable and allocable. The terms of the agreement contained multiple, distinct performance obligations, including transfer of a license for the Territory, research and development oversight for the trials run by Ventagen, and clinical data sharing.

The Company estimated the transaction prices, including any variable consideration, at contract inception and determined the fair value of such obligations. The performance obligation associated with the license transfer was satisfied at a point in time, or at contract inception; however, the Company assigned no value to the license transfer. The remaining $1,000 transaction price was allocated between the research and development oversight and clinical data sharing. The Company is recognizing revenue for these obligations over an 8-year period, beginning in 2015, by measuring the progress towards satisfaction of the performance obligations. As clinical oversight and clinical data sharing occurs over the 8-year clinical trial period, the revenue is recognized over the same period in which the cost for these services is incurred.

The Company defers recognition of the portion of the $1,000 non-refundable upfront license fee for the portion of the performance obligations that are not satisfied. The Company recognized revenue of $31 and $63 in each of the three and six months ended June 30, 2022, respectively. The Company recognized revenue of $31 and $63 in each of the three and six months ended June 30, 2021, respectively. The license agreement includes a $2,500 potential future milestone payment due to the Company upon successful completion of certain separate, distinct events. At this time, the Company cannot estimate when the milestone-related performance obligations are expected to be achieved and will recognize revenue once satisfaction is probable. There was no additional variable consideration, significant financing components, non-cash consideration, or consideration payable to the customer in this agreement.

14. 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 $750 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 to MGB to be applied toward the Company's on-going obligations to reimburse patent expenses. In six months ended June 30, 2022 and 2021, respectively, the Company expensed $0 and $28, respectively, for 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 $100 and agreed to reimburse patent costs incurred by MGB, including $141 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 beginning following the fourth anniversary of the effective date. The MGB License contains cumulative milestone payments equaling a maximum amount of $39,000 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.

15. 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 June 30, 2022, 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

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

16. Net loss per share

Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
Numerator:	**2022**	**2021**	**2022**	**2021**
Net loss attributable to common stockholders	$ (4,149)	$ (17,080)	$ (5,023)	$ (21,558)
Denominator:				
Weighted-average shares of common stock outstanding-basic and diluted	28,810,224	11,720,530	28,750,431	11,684,374
Net loss per share attributed to common stockholders-basic and diluted	$ (0.14)	$ (1.46)	$ (0.17)	$ (1.85)

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 attributable to common stockholders is the same.

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

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2022	**2021**	**2022**	**2021**
Series B preferred stock (as converted to common stock)	-	4,538,578	-	4,538,578
Series C preferred stock (as converted to common stock)	-	2,454,195	-	2,454,195
Outstanding warrants for common stock	7,507,708	7,524,270	7,507,708	7,524,270
Outstanding stock options (as converted to common stock)	5,650,785	4,608,332	5,650,785	4,608,332
	13,158,493	19,125,375	13,158,493	19,125,375

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 financial statements and the related notes and other financial information included elsewhere in this 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 late clinical stage biopharmaceutical company focused on helping patients fight cancer with oncolytic viral immunotherapies. Our engineered viruses are designed to induce immunogenic 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. Our approach combines an in-depth knowledge of viral immunotherapy with extensive clinical experience across a wide range of indications. Based on the broad range of data that we have generated from our preclinical models and clinical trials using our approach, we have observed what we believe to be systemic immune response against locally injected tumors and their distant metastases. We have established two oncolytic viral immunotherapy platforms based on novel, genetically modified adenovirus and herpes simplex virus (HSV) constructs. In our clinical results to date from CAN-2409, our lead adenovirus product candidate, and CAN-3110, our lead product candidate from our HSV platform, we have observed that these candidates may have the potential to address significant unmet patient need and improve clinical outcomes in novel indications across broader patient populations.

In non-small cell lung cancer (NSCLC), we have previously observed monotherapy activity of CAN-2409 in a Phase 1 biomarker focused window of opportunity trial. In 2020, we initiated a Phase 2 clinical trial evaluating CAN-2409 plus valacyclovir in combination with PD-(L)1 checkpoint inhibitors for patients with inadequate response to PD-(L)1 checkpoint inhibitors. This open label trial is targeting enrollment of approximately 96 patients with stage III/IV NSCLC in three separate cohorts. The cohorts are defined based on response to checkpoint inhibitors at the time of enrollment. Patients will continue treatment with their initial checkpoint inhibitor and CAN-2409 will be added to their regimen. The primary efficacy endpoint for this trial is response rate measured by response evaluation criteria in solid tumors (RECIST). At the American Society for Clinical Oncology (ASCO) in June 2022, the Company reported initial data, as of April 20, 2022, from 35 enrolled patients, of which 20 were evaluable for efficacy. A summary of the data is as follows

- Disease control rate of 87.5% achieved in patients who were all progressing on anti-PD-1 therapy at trial entry.
- Evidence of tumor regression in both injected and uninjected lesions.
- Partial response in 3 (15%) patients.
- CAN-2409 was well tolerated with no treatment-related grade 4 adverse events reported and grade 3 adverse events in three patients.

We anticipate presenting updated clinical data from this trial in the fourth quarter of 2022.

We are also evaluating CAN-2409 in newly diagnosed high-grade glioma. The FDA has granted CAN-2409 fast track designation for use in this setting in combination with standard of care surgery and chemoradiation. We intend to initiate a potentially registrational Phase 3 trial in this indication in the third quarter of 2022. The randomized placebo-controlled trial will compare CAN-2409 paired with prodrug (valacyclovir), surgery and radiotherapy, and temozolomide for patients with methylated MGMT promoters for whom temozolomide is indicated, to a control arm where CAN-2409 will be replaced by a placebo in the treatment regimen. This trial will be randomized at a ratio of 1 to 1 in the active versus control arms and will assess efficacy based on overall survival. It is intended to enroll approximately 600 patients.

Interim data from a fully accrued Phase 1b trial of CAN-2409 in combination with nivolumab, valacyclovir and standard of care treatment in patients with newly diagnosed high-grade glioma are anticipated in the fourth quarter of 2022. Nivolumab previously failed to meet the primary endpoint of improved median overall survival in a separate 369 patient Phase 3 glioblastoma trial suggesting the challenge of eliciting an immune effect in brain cancer with systemically administered checkpoint inhibitors.

Our most advanced product candidate, CAN-2409, is an off-the-shelf adenovirus product candidate combined with the prodrug valacyclovir that has generated promising clinical activity across a range of solid tumor indications, including our lead indication of prostate cancer. We are currently conducting, as part of our most advanced CAN-2409 program, a Phase 3 clinical trial in the United States under a Special Protocol Assessment, or SPA, with the U.S. Food and Drug Administration (FDA) for CAN-2409 in patients with newly diagnosed localized prostate cancer who have an intermediate- or high-risk for progression. We completed enrollment for this trial in September 2021 and we expect a final data readout at the end of 2024.

In addition, we are advancing development of our HSV platform product candidates for solid tumor indications. Our lead HSV product candidate, CAN-3110, is currently in an ongoing investigator-initiated Phase 1 clinical trial in our initial target indication of recurrent high-grade glioma. Initial clinical data from this trial was presented in an oral presentation at ASCO in June 2021, and we reported additional biomarker data in November 2021. We anticipate clinical data from additional patients in the fourth quarter of 2022. We are also designing other novel oncolytic viral immunotherapy candidates using our enLIGHTEN platform that is based on HSV.

Our oncolytic viral immunotherapy approach utilizes intratumoral administration of genetically engineered viruses to selectively induce tumor cell death and elicit an innate and adaptive anti-tumor immune 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. In our data from our clinical studies in patients with cancer, we have observed increases in the expression of immune checkpoints PD-1, PD-L1 and CTLA-4 following treatment with CAN-2409 supporting the evaluation of combinations with immune checkpoint inhibitors (ICI) such as anti-PD-(L)1 that, typically, are only efficacious in patients with immunologically "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 CAN-2409 and CAN-3110 to induce systemic immune response against distal, uninjected tumors, also known as an "abscopal" effect.

We believe oncolytic viral immunotherapy is among the most promising cancer treatment modalities today. Treatment with oncolytic viral immunotherapy has already been clinically validated through talimogene laherparepvec (IMLYGIC, Amgen), the first FDA-approved intratumoral oncolytic virus. Our goal is to further improve patient outcomes from oncolytic 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, and storage conditions that could potentially lower logistical barriers for patients and clinicians.

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, as well as certain physical property and equipment. 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).

MGB. On January 20, 2018, we entered into an exclusive option agreement, or the Option Agreement, with MGB. Pursuant to the Option Agreement, we obtained the exclusive right from MGB to negotiate an exclusive worldwide, 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, or 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, or the MGB Clinical Trial Agreement, on June 19, 2018. Under the MGB Clinical Trial Agreement, we have committed to remitting up to $750,000 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, or 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, or the Licensed Products and otherwise practice processes covered by such licensed patents, or 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 of $100,000. We 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, or the Ventagen Agreement, with Ventagen, LLC, or Ventagen. The Ventagen Agreement provides Ventagen an exclusive license, with rights to grant sublicenses (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 Licensed Products, for commercial sale and distribution within Mexico, Belize, Guatemala, Honduras, El Salvador, Costa Rica, Nicaragua, Panama, Colombia and Bolivia.

Impact of COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of the novel coronavirus, or COVID-19, a global pandemic, or the COVID-19 pandemic, which continues to spread throughout the United States and worldwide. The ultimate extent of the impact of the COVID-19 pandemic on our business, financial condition and results of operations is highly uncertain and will depend on future developments that cannot be predicted, including new information that may emerge concerning the severity of COVID-19 and actions taken by government authorities and businesses to contain or prevent the further spread of COVID-19. For instance, a recurrence or continuation of COVID-19 cases, including new variants, could cause a more widespread or severe impact on commercial activity depending on where infection rates are highest. If we or any of the third parties with whom we engage were to experience any additional shutdowns or other prolonged business disruptions as a result of the ongoing COVID-19 pandemic, our ability to conduct our business in the manner and on the timelines presently planned could be materially or negatively affected, which could have a material adverse impact on our business, results of operations and financial condition.

We have been carefully monitoring the ongoing COVID-19 pandemic and its impact on our business and have taken important steps to help ensure the safety of our employees and their families and to reduce the spread of COVID-19. We have established a flexible work policy for all employees under which we encourage all of our employees to work from the office or home as they feel appropriate. Those employees performing or supporting business-critical operations, such as certain members of our laboratory and facilities staff are working on site on a daily basis. For those employees, who come to work at our facility, we have implemented stringent safety measures designed to comply with applicable federal, state and local guidelines instituted in response to the COVID-19 pandemic. We have also maintained efficient communication with our partners and clinical sites during the COVID-19 pandemic. We have taken these precautionary steps while maintaining business continuity so that we can continue to make progress on our programs. While we have experienced delays in enrollment and site closures at certain of our third-party clinical trial sites, these delays have not had a material impact on our development timelines for our product candidates. We will continue to monitor developments as we address the disruptions and uncertainties relating to the COVID-19 pandemic. See the “Risk Factors” section for a discussion of the potential adverse impact of the COVID-19 pandemic on our business, financial condition and results of operations.

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. We are recognizing as research and development service revenue $1.0 million that we received in 2014 and 2015 from Ventagen for an exclusive license to develop products for commercial sale and development within certain countries. The $1.0 million is being recognized as revenue over the period during which we provide services under the license agreement.

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 including payments to contract manufacturing organizations (CMOs) for the commercial scale manufacturing or our product candidate CAN-2409. 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 CMOs for the commercial manufacture of our product candidate CAN-2409 and the clinical scale manufacture of our product candidate CAN-3110 as well as complete the development, construction and qualification of our clinical manufacturing facility in Needham;
- 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 the ongoing COVID-19 pandemic or similar public health crisis;
- 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; director and officer insurance costs; 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. We also expect to incur increased expenses associated with being a public company as a result of our initial public offering, or the IPO, including costs of accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission, or 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 National Institute of Health for development of CAN-2409 for use as a therapy for pancreatic cancer.

Interest, dividend, and investment income (expense), net

Interest, dividend and investment income consists of amounts earned on investment of cash equivalents and short-term investments and is net of interest payments made on our debt.

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. 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. 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, 2021, we had federal net operating loss carryforwards, or NOLs, of approximately $51.6 million and state NOLs of approximately $48.4 million which may be available to offset future taxable income. Our federal NOLs include $8.8 million available to reduce future taxable income through 2028 and approximately $42.8 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 2032. As of December 31, 2021, we also had federal and state research and development tax credit carryforwards of $2.0 million and $1.1 million, respectively, which are available to offset federal and state tax liabilities through 2036 and 2028, 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 June 30, 2022 and December 31, 2021.

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 shareholders 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, or 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, or Section 382, results from transactions increasing the ownership of certain shareholders 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. 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.

Results of Operations

Comparison of three and six months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the three and six months ended June 30, 2022 and 2021 (in thousands):

	THREE MONTHS ENDED JUNE 30,		INCREASE/ (DECREASE)	SIX MONTHS ENDED JUNE 30,		INCREASE/ (DECREASE)
	2022	2021		2022	2021	
Research and development service revenue	$ 31	$ 31	$ —	$ 63	$ 63	$ —
Operating expenses:						
Research and development	5,022	3,292	1,730	10,438	6,048	4,390
General and administrative	3,762	2,040	1,722	7,364	3,972	3,392
Total operating expenses	8,784	5,332	3,452	17,802	10,020	7,782
Loss from operations	(8,753)	(5,301)	(3,452)	(17,739)	(9,957)	(7,782)
Grant income	—	605	(605)	—	796	(796)
Interest, dividend and investment income, net	(365)	(15)	(350)	(540)	(28)	(512)
Change in fair value of warrant liability	4,969	(12,369)	17,338	13,256	(12,369)	25,625
Net loss	$ (4,149)	$ (17,080)	$ 12,931	$ (5,023)	$ (21,558)	$ 16,535

Revenue

We had research and development service revenue of $31,000 for each of the three months ended June 30, 2022 and 2021. This represents the recognition as research and development service revenue of a portion of the $1.0 million that we received in 2014 and 2015 from Ventagen, a related party, which is being recognized over the period during which we provide the services.

Research and development expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2022 and 2021 (in thousands):

	THREE MONTHS ENDED JUNE 30,		INCREASE (DECREASE)
	2022	2021	
Employee-related	$ 2,828	$ 2,165	$ 663
Clinical development	1,540	914	626
Depreciation of fixed assets	187	—	187
Pre-clinical research	176	8	168
Recruiting	117	77	40
Occupancy	110	128	(18)
Other	64	—	64
	$ 5,022	$ 3,292	$ 1,730

Research and development expenses for the three months ended June 30, 2022 were $5.0 million, compared with $3.3 million for the three months ended June 30, 2021 and consisted primarily of $2.8 million and $2.2 million, respectively, of employee-related costs, including $57,000 and $400,000, respectively, of non-cash stock compensation expense, $1,540,000 and $914,000, respectively, of clinical development costs related to our clinical trial sites and the cost of treating and following up on patients in our clinical trials, regulatory and manufacturing expenses, $187,000 and $0, respectively, of depreciation, $176,000 and $8,000, respectively, of preclinical research costs associated with our development programs, $117,000 and $77,000, respectively, of recruiting expenses, and $110,000 and $128,000, respectively, of occupancy costs. The increase of $1.7 million was primarily related to $663,000 increase in employee-related costs due to an increase in research and development headcount, $626,000 increase in clinical development costs which was primarily driven by increased manufacturing and regulatory costs, $187,000 increase in depreciation primarily related to depreciation of lab equipment and leasehold improvements, and $168,000 increase in preclinical research.

General and administrative expenses

The following table summarizes our general and administrative expenses for the three months ended June 30, 2022 and 2021 (in thousands):

	THREE MONTHS ENDED JUNE 30,		INCREASE (DECREASE)
	2022	2021	
Employee-related	$ 1,647	$ 1,487	$ 160
Professional and consulting fees	771	364	407
Insurance	703	7	696
Recruiting	422	5	417
Other	219	177	42
	$ 3,762	$ 2,040	$ 1,722

General and administrative expenses were $3.8 million for the three months ended June 30, 2022 compared with $2.0 million for the three months ended June 30, 2021 and consisted primarily of $1.6 million and $1.5 million, respectively, of employee-related costs, including $381,000 and $669,000, respectively, of non-cash stock compensation expense, $771,000 and $364,000, respectively, of professional and consulting fees, $703,000 and $7,000, respectively, of insurance costs, and $422,000 and $5,000, respectively of recruiting costs. The increase of $1.7 million was primarily due to an increase of $696,000 in insurance expense, $417,000 in recruiting expenses, $407,000 in professional and consulting fees, and $160,000 in employee related costs as we increased our general and administrative headcount to manage growth and operate as a public company. Insurance expense increased due to the cost of directors and officers insurance upon completion of the IPO. The increase in recruiting fees was primarily due to a search for three new members of our Board of Directors. The increase in professional and consulting fees was primarily due to an increase in fees paid to investor and public relations consultants and to legal and accounting firms.

Grant income

Grant income was $0 and $605,000 for the three months ended June 30, 2022 and 2021, respectively. Grant income for the three months ended June 30, 2021 represents amounts received under a grant from the National Institutes of Health for development of CAN-2409 for use as a therapy for pancreatic cancer. This grant was completed as of December 31, 2021.

Interest, dividend and investment expense, net

Interest, dividend and investment expense was $365,000 for the three months ended June 30, 2022 compared with an expense of $15,000 for the three months ended June 30, 2021 and represents the interest expense on our debt obligations, which is net of earnings on our cash equivalents. The increase was primarily due to increased interest expense incurred as a result of increased borrowing in the first quarter of 2022.

Change in fair value of warrant liability

The change in fair value of our warrant liability was a decrease in value of $5.0 million for the three months ended June 30, 2022 compared with an increase in value of $12.4 million for the three months ended June 30, 2021. The decrease in the warrant liability value for the three months ended June 30, 2022 was primarily due to the decrease in our stock price from March 31, 2022 to June 30, 2022. The increase in the warrant liability value for the three months ended June 30, 2021 was primarily due to the increase in the valuation of our company from March 31, 2021 to June 30, 2021.

Comparison of six months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021 (in thousands):

	THREE MONTHS ENDED JUNE 30,		INCREASE/ (DECREASE)	SIX MONTHS ENDED JUNE 30,		INCREASE/ (DECREASE)
	2022	2021		2022	2021	
Research and development service revenue	$ 31	$ 31	$ —	$ 63	$ 63	$ —
Operating expenses:						
Research and development	5,022	3,292	1,730	10,438	6,048	4,390
General and administrative	3,762	2,040	1,722	7,364	3,972	3,392
Total operating expenses	8,784	5,332	3,452	17,802	10,020	7,782
Loss from operations	(8,753)	(5,301)	(3,452)	(17,739)	(9,957)	(7,782)
Grant income	—	605	(605)	—	796	(796)
Interest, dividend and investment income, net	(365)	(15)	(350)	(540)	(28)	(512)
Change in fair value of warrant liability	4,969	(12,369)	17,338	13,256	(12,369)	25,625
Net loss	$ (4,149)	$ (17,080)	$ 12,931	$ (5,023)	$ (21,558)	$ 16,535

Revenue

We had research and development service revenue of $63,000 for each of the six months ended June 30, 2022 and 2021. This represents the recognition as research and development service revenue of a portion of the $1.0 million that we received in 2014 and 2015 from Ventagen, a related party, which is being recognized over the period during which we provide the services.

Research and development expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2022 and 2021 (in thousands):

	SIX MONTHS ENDED JUNE 30,		INCREASE (DECREASE)
	2022	2021	
Employee-related	$ 6,578	$ 3,661	$ 2,917
Clinical development	2,579	1,770	809
Pre-clinical research	375	80	295
Depreciation of fixed assets	352	—	352
Occupancy	224	257	(33)
Recruiting	196	280	(84)
Other	134	—	134
	$ 10,438	$ 6,048	$ 4,390

Research and development expenses for the six months ended June 30, 2022 were $10.4 million, compared with $6.0 million for the six months ended June 30, 2021 and consisted primarily of $6.6 million and $3.7 million, respectively, of employee-related costs, including $199,000 and $516,000, respectively, of non-cash stock compensation expense, $2.6 million and $1.8 million, respectively, of clinical development costs related to our clinical trial sites and the cost of treating and following up on patients in

our clinical trials, regulatory, and manufacturing expenses, $375,000 and $80,000, respectively, of preclinical research costs associated with our development programs, $352,000 and $0, respectively, of depreciation, $224,000 and $257,000, respectively, of occupancy costs, and $196,000 and $280,000, respectively, of recruiting expenses. The increase of $4.4 million was primarily related to $2.9 million increase in employee-related costs due to an increase in research and development headcount and $1.0 million in severance associated with the termination of our former Chief Scientific Officer and Chief Medical Officer in February 2022, $809,000 increase in clinical development costs which was primarily driven by increased manufacturing and regulatory costs, $352,000 increase to depreciation primarily related to depreciation of lab equipment and leasehold improvements, and a $295,000 increase in preclinical research. These increases were partially offset by a decrease of $84,000 in recruiting costs.

General and administrative expenses

The following table summarizes our general and administrative expenses for the six months ended June 30, 2022 and 2021 (in thousands):

	SIX MONTHS ENDED June 30,		INCREASE (DECREASE)
	2022	2021	
Employee-related	$ 3,219	$ 2,517	$ 702
Professional and consulting fees	1,812	1,113	699
Insurance	1,402	14	1,388
Recruiting	496	5	491
Other	435	323	112
	$ 7,364	$ 3,972	$ 3,392

General and administrative expenses were $7.4 million for the six months ended June 30, 2022 compared with $4.0 million for the six months ended June 30, 2021 and consisted primarily of $3.2 million and $2.5 million, respectively, of employee-related costs, including $730,000 and $984,000, respectively, of non-cash stock compensation expense, $1.8 million and $1.1 million, respectively, of professional and consulting fees, $1.4 million and $14,000, respectively, of insurance costs, and $496,000 and $5,000 of recruiting fees. The increase of $3.4 million was primarily due to increases of $1.4 million in insurance expense, $702,000 in employee related costs as we increased our general and administrative headcount to manage growth and operate as a public company, $699,000 in professional and consulting fees, and $491,000 in recruiting fees. Insurance expense increased due to the cost of directors and officers insurance upon completion of the IPO. The increase in professional and consulting fees is primarily due to an increase in fees paid to investor and public relations consultants and legal and accounting firms. The increase in recruiting costs is primarily due to a search for three new members of our Board of Directors.

Grant income

Grant income was $0 and $796,000 for the six months ended June 30, 2022 and 2021, respectively. Grant income for the six months ended June 30, 2021 represents amounts received under a grant from the National Institutes of Health for development of CAN-2409 for use as a therapy for pancreatic cancer. This grant was completed as of December 31, 2021.

Interest, dividend and investment expense, net

Interest, dividend and investment expense was $540,000 for the six months ended June 30, 2022 compared with an expense of $28,000 for the six months ended June 30, 2021 and represents the interest expense on our debt obligations, which is net of earnings on our cash equivalents. The increase is primarily due to increased interest expense incurred as a result of increased borrowing in the first quarter of 2022.

Change in fair value of warrant liability

The change in fair value of our warrant liability was a decrease in value of $13.3 million for the six months ended June 30, 2022 compared to an increase in value of $12.4 million for the six months ended June 30, 2021. The decrease in the warrant liability value for the six months ended June 30, 2022 is primarily due to the decrease in our stock price from December 31, 2021 to June 30, 2022. The increase in the warrant liability value for the six months ended June 30, 2021 is primarily due to the increase in the Company's valuation from December 31, 2020 to June 30, 2021.

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 will 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 clinical 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.

We do not currently have any approved products and have never generated any revenue from wproduct sales. We have financed our operations primarily through government grants and proceeds from the sale of convertible notes, sales of common stock and our convertible preferred stock, and proceeds from debt financing with Silicon Valley Bank ("SVB"). As of June 30, 2022, we have raised approximately $160.6 million, including $15.4 million of government grants, $66.1 million from the sale of convertible preferred stock, and $79.1 million from the sale of our common stock in our IPO. In addition, in February 2022, we borrowed $20.0 million under the loan and security agreement, or the Loan Agreement, with SVB. Our cash and cash equivalents totaled $86.8 million as of June 30, 2022. We had $20.6 million of long-term debt as of June 30, 2022.

Cash flows

The following table summarizes our sources and uses of cash for the six months ended June 30, 2022 and 2021 (in thousands):

	SIX MONTHS ENDED JUNE 30,	
	2022	2021
Net cash used in operating activities	$ (15,150)	$ (10,086)
Net cash used in investing activities	(806)	(939)
Net cash provided by financing activities	19,938	445
Net increase (decrease) in cash and cash equivalents	$ 3,982	$ (10,580)

Cash flows for the six months ended June 30, 2022 and 2021

Operating activities

Net cash used in operating activities for the six months ended June 30, 2022 was $15.2 million, primarily consisting of a net loss of $5.0 million as we incurred expenses associated with our clinical programs, increased headcount and incurred costs associated with operating as a public company. In addition, we had non-cash income of $13.3 million as a result of the change in the fair value of our warrant liability. Non-cash income was partially offset by $1.5 million in non-cash charges primarily related to depreciation and non-cash stock compensation expense. Net cash used in operating activities was also impacted by $1.6 million in changes in operating assets and liabilities, primarily driven by a decrease of $1.8 million in prepaids and other current assets.

Net cash used in operating activities for the six months ended June 30, 2021 was $10.1 million, primarily consisting of a net loss of $21.6 million and non-cash charges of $13.5 million primarily as a result of the $12.4 million expense as a result of the change in the fair value of our warrant liability and $1.4 million of non-cash stock compensation expense which was partially offset by $464,000 from the forgiveness of the Paycheck Protection loan. Net cash used in operating activities was also impacted by $2.0 million in changes in operating assets and liabilities, primarily driven by a decrease of $1.2 million in accrued expenses and an increase of $506,000 in other long term assets.

Investing activities

Net cash used in investing activities for the six months ended June 30, 2022 was $806,000 and consisted of the purchase of fixed assets.

Net cash used in investing activities for the six months ended June 30, 2021 was $939,000 and consisted of the purchase of fixed assets.

Financing activities

Net cash provided by financing activities for the six months ended June 30, 2022 was $19.9 million and primarily consisted of $19.9 million of net proceeds from a term loan with a bank.

Net cash provided by financing activities for the six months ended June 30, 2021 was $445,000 and consisted of $410,000 of proceeds from exercise of warrants and $35,000 of proceeds from the exercise of stock options.

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, develop our manufacturing capabilities with a CMO and build our laboratory and clinical manufacturing facility, 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;
- pursue the preclinical and clinical development of other product candidates using our HSV platform;
- develop our manufacturing capabilities, including establishing a relationship with a contract manufacturer for commercial manufacturing of our product candidate CAN-2409 and the construction of our laboratory and clinical manufacturing facility for our product candidate CAN-3110; 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 June 30, 2022, will enable us to fund our operating expenses and capital expenditure requirements into the first 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 process development for our manufacturing capabilities;
- the scope, progress, results, and costs of any product candidates that we may derive from our HSV 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 preferred 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. 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

The following is a summary of our contractual obligations and commitments as of June 30, 2022:

	PAYMENTS DUE BY PERIOD (in thousands)			
	TOTAL	LESS THAN 1 YEAR	1 TO 3 YEARS	3 TO 5 YEARS
Operating lease obligation [1]	$ 2,495	$ 575	$ 1,195	$ 724
Total	$ 2,495	$ 575	$ 1,195	$ 724

[1] Represents future minimum lease payments under our operating lease for office and laboratory space at our Needham, Massachusetts facility.

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, or U.S. GAAP. The preparation of our 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.

While our significant accounting policies are described in more detail in the notes to our condensed consolidated financial statements included elsewhere in this Form 10-Q, we believe that the following accounting policies are those most significant to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. Most of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to the following:

- clinical trial sites where patients are being treated with our product candidates; and
- consultants providing services related to process development, regulatory and other services.
- CMO's who are manufacturing commercial scale quantities of our product candidates

Actual services performed may vary from our estimates, resulting in adjustments to research and development costs or inventories in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our results of operations.

Determination of fair value of warrants

In connection with the Series B convertible preferred stock issuance in November 2018, the Company issued warrants to purchase shares of common stock of which certain warrants are shown as a liability on the balance sheet. The fair value of the warrants was 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 prior to the IPO, risk-free interest rate, expected dividend yield, expected volatility of the price of the underlying preferred stock, and the remaining contractual term of the warrants. The most significant assumption in the model impacting the fair value of the common stock warrants is the fair value of the Company's common stock as of each remeasurement date. Prior to the IPO, the Company determined the fair value per share of the underlying common stock by taking into consideration the most recent sales of preferred stock, results obtained from third-party valuations and additional factors that were deemed relevant.

Stock-based compensation

We measure stock options and other stock-based awards granted to our employees, directors, consultants, advisors based on the fair value on the date of the grant, awards, net of actual forfeitures, over the requisite service period, which is generally the vesting period of the respective award. For stock-based awards granted to non-employees, compensation expense is recognized over the vesting period which approximates the period over which services are rendered by such non-employees.

We estimate the fair value of each stock option grant on the date of grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the expected volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, and our expected dividend yield.

Determination of fair value of common stock

Prior to the IPO, there had been no public market for our common stock and as such, the estimated fair value of our common stock had been determined by our board of directors as of the date of each option grant, with input from management, taking into consideration our most recently available third-party valuations of common stock at the time of the grants, as well as our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. Third-party valuations, or valuation reports, were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.

For the December 1, 2020, January 1, 2021, and June 15, 2021 third-party prepared valuation reports, a probability-weighted expected return method was used to determine the fair value of the common stock. The present value of the common stock under each of these three identified scenarios was weighted based on the probability of each scenario occurring to determine the value of the common stock. These third-party valuations resulted in a valuation of our common stock of $3.96, $4.97 and $6.64 per share as of December 1, 2020, January 1, 2021 and June 15, 2021, respectively.

In addition to considering the results of the valuation reports, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold shares of convertible preferred stock and the superior rights and preferences of the convertible preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status and results of preclinical studies and clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biotechnology industry and trends within that industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our convertible preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company considering prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biotechnology industry.

The assumptions underlying these valuations were highly complex and subjective and represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used

different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could be materially different.

Subsequent to the IPO, a public trading market for our common stock has been established and it is no longer necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock is determined based on the quoted market price of our common stock.

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, or 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, or 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 $1.07 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) December 31, 2026.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Act of 1934 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, or 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 Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2022. Based on the evaluation of our disclosure controls and procedures as of June 30, 2022, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control Over Financial Reporting

In preparation of our financial statements to meet the requirements of our IPO, we determined that material weaknesses in our internal control over financial reporting existed during fiscal 2020 and 2021 and remain unremediated as of June 30, 2022. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis. The material weaknesses we identified are related to;

(1) the fact that we did not have sufficient finance and accounting staff with U.S. GAAP technical and accounting expertise to evaluate and account for significant transactions and oversee our third-party consultants. As a result we did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose certain complex transactions, which led to inappropriate accounting conclusions associated with stock compensation expenses.
(2) the fact that we lacked proper monitoring of entity level controls and segregation of duties due to our small accounting staff.

Remediation Activities

Management has been actively engaged in remediating the above described material weaknesses. The following remedial actions have been taken as of June 30, 2022:

(1) We hired an experienced Chief Financial Officer in December 2020 with experience serving as acting chief financial officer of a public company and serving as an audit partner at a major accounting firm and we hired a Controller in November 2021 with experience working at a public company and as a manager at a major public accounting firm.

(2) We strengthened supervisory reviews by our financial management.

(3) We expanded our accounting and finance team to add additional qualified accounting and finance resources, including augmenting our finance team with third-party consultants that possess the required expertise to assist management with their review, as necessary.

The process of implementing an effective financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a financial reporting system that is adequate to satisfy our reporting obligations. As we continue to evaluate and take actions to improve our internal control over financial reporting, we may take additional actions to address control deficiencies. This will include the hiring of additional qualified personnel and implementation of a new accounting system.

While progress has been made to enhance our internal control over financial reporting, we are still in the process of implementing these processes, procedures and controls. Additional time is required to complete implementation and to assess and ensure the sustainability of these procedures. We believe the above actions will be effective in remediating the material weaknesses described above and we will continue to devote significant time and attention to these remedial efforts. However, the material weaknesses cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded that these controls are operating effectively.

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 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.

We are not subject to any material legal proceedings.

Item 1A. Risk Factors.

Our future operating results could differ materially from the results described in this Quarterly Report on Form 10-Q due to the risks and uncertainties described below. You should consider carefully the following information about risks below in evaluating our business. If any of the following risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. 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 IPO. From our inception through June 30, 2022, we raised an aggregate of $145.2 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 June 30, 2022, our cash and cash equivalents were $86.8 million. We have incurred net losses in each year since our inception, and we had an accumulated deficit of $85.3 million as of June 30, 2022. For the six months ended June 30, 2022 and 2021, we reported net losses of $5.0 million and $21.6 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' deficit 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 the ongoing COVID-19 pandemic;
- 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 and commercial and clinical scale 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 oncolytic viral immunotherapy programs;
- timely file and receive acceptance of our Investigational New Drug applications, or INDs, in order to commence our planned clinical trials or future clinical trials;
- successfully enroll subjects in, and complete, clinical trials for our oncolytic viral immunotherapy programs;
- implement measures to help minimize the risk of COVID-19 to our employees as well as patients enrolled in our clinical trials;
- timely file NDAs 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.

We will need to raise substantial additional funding. 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 are currently conducting a Phase 3 clinical trial for CAN-2409 in newly diagnosed localized prostate cancer in intermediate and high-risk patients for which we completed enrollment in September of 2021 and expect to receive final data readout in the end of 2024. Our second program using CAN-2409 is for the treatment of a type of brain cancer called high-grade glioma. We expect to be ready to initiate a potentially registrational Phase 3 clinical trial in this indication in the third quarter of 2022. Our third program using CAN-2409 is for the treatment of NSCLC. We have an ongoing Phase 2 trial and initial clinical data was presented at ASCO in June 2022. If the Phase 2 clinical trial is positive, this may warrant the initiation of a potentially registrational Phase 3 clinical trial. Consequently, 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 operations into the first 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 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, pancreatic cancer, and high-grade glioma as well as for CAN-3110 in our initial target indication of recurrent high-grade glioma 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 potential additional expenses attributable to adjusting our development plans (including any supply related matters) to the COVID-19 pandemic;
- 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 oncolytic viral immunotherapies as well as immuno-oncology therapies in general and other adverse market developments;
- the costs of transitioning our clinical manufacturing operations to our new facility;

- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates; and
- the ongoing impact of the COVID-19 pandemic, 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.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Disruptions in the financial markets in general, and more recently due to the ongoing COVID-19 pandemic, have made equity and debt financing more difficult to obtain, and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will 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. 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 funding at acceptable terms on a timely basis, we may be required to significantly curtail, delay, or discontinue one or more of our research or development programs or the commercialization of any product candidate or 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 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 SVB 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 SVB 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 SVB 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, which could have a material adverse effect on our business, financial condition, and results of operations.

Recent increases in interest rates has 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 SVB 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.

Risks Related to Product Development

Our business is dependent on the success of our lead 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 lead product candidate. We are currently conducting, as part of our most advanced CAN-2409 program, a Phase 3 clinical trial under an SPA for CAN-2409 in patients with newly diagnosed localized prostate cancer who have an intermediate or high-risk for progression. We completed enrollment for this trial in September 2021 and expect to receive a final data readout at the end of 2024. We are also conducting a Phase 2 clinical trial of CAN-2409 in patients with NSCLC in combination with immune checkpoint inhibitors. We presented initial clinical data from this trial at ASCO, in June 2022. We are also evaluating CAN-2409 in high-grade glioma and expect to be ready to initiate a potentially registrational Phase 3 trial in this indication in the third quarter of 2022. Additionally, we have an ongoing investigator-initiated Phase 1 clinical trial for CAN-3110, our most advanced HSV product candidate, in recurrent high-grade glioma and reported additional biomarker results in November of 2021. 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, build out 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 Phase 3 clinical trials for CAN-2409 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 have been transient, injection site-related 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 or blood abnormalities. Those include pyrexia, genitourinary toxicity, increased AST/ALT, increased bilirubin, hemiparesis, worsening of speech impairment, 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, top line 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, top line 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 top line or preliminary results of primary and key secondary endpoints before the final trial results are completed. Preliminary, top line and interim data from our clinical trials may change as more patient data or analyses become available. Preliminary, top line 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 top line 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.

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 immune checkpoint inhibitors. 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 all of our research and development efforts on our CAN-2409 and CAN-3110 product candidates, and our future success 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 oncolytic 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 oncolytic 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 oncolytic 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 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. 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 with CAN-2409 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 a 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, oncolytic viral immunotherapy, could damage public perception of any of our product candidates and negatively affect our business.

The commercial success of adenovirus- or oHSV-based product candidates will depend in part on public acceptance of the use of immuno-oncology, and, in particular, oncolytic viral immunotherapy. Adverse events in clinical trials of CAN-2409, CAN-3110 or any other adenovirus- or oHSV-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 oHSV-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 oncolytic 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-2409 and 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 significantly delayed by the ongoing COVID-19 pandemic 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 the ongoing COVID-19 pandemic, 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, oncolytic 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, oncolytic 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 oncolytic 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 oncolytic viral immunotherapy with adenovirus and HSV. Other competitive products and therapies are based on entirely different approaches. We are aware that Oncorus, Replimune, Amgen, Immavir, Fergene and IconOVir, among others, are developing oncolytic 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 institutional review board, or 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 or 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 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 Phase 3 clinical trial of CAN-2409 in newly diagnosed localized prostate cancer in intermediate- and high-risk patients in combination with the standard of care through an 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.

We have obtained orphan drug designation for CAN-2409 for use in combination with an anti-herpetic prodrug for treatment of malignant brain tumors; however, we may be unable to maintain this designation or obtain orphan drug designation for our other product candidates, and we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.

As part of our business strategy, we sought and have received orphan drug designation for CAN-2409 for use in combination with an anti-herpetic prodrug for treatment of malignant brain tumors; however, we may not be able to maintain this status. We may also seek additional orphan drug designations for CAN-2409 and for certain of our future product candidates, and we may be unsuccessful in obtaining such designations. Regulatory authorities in some jurisdictions, including the United States and other major markets, may designate drugs and biologics intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Commission grants orphan drug designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan drug designation application. Orphan drug designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug or biologic no longer meets the criteria for orphan drug designation or if the drug or biologic is sufficiently profitable such that market exclusivity is no longer justified. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even though we have obtained orphan drug designation for CAN-2409 for use in combination with an anti-herpetic prodrug for treatment of malignant brain tumors, and even if we are able to obtain orphan drug exclusivity for a future product candidate, that exclusivity may not effectively protect the relevant product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label for the orphan disease. Even after an orphan drug is approved, the FDA may subsequently approve another product for the same condition if the FDA concludes that the latter product is not the same product or is clinically superior to the protected orphan drug because it is shown to be safer or more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the orphan indication for which it was designated. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we have obtained orphan drug designation for CAN-2409 for use in combination with an anti-herpetic prodrug for treatment of malignant brain tumors, we may not be able to maintain such designation; and while we may seek orphan drug designation for applicable indications for any future product candidates, we may never receive such designations. Even though we have received such designation for CAN-2409, and may receive further such designations in the future, there is no guarantee that we will enjoy the benefits of those designations. In addition, the FDA may reevaluate its regulations and policies under the Orphan Drug Act. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A fast track designation by the FDA, even though granted for CAN-2409, 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 the treatment of localized,

primary prostate cancer in combination with radiation therapy to improve the local control rate, as well as for CAN-2409 in combination with standard of care surgery and chemoradiation to improve survival in adults with newly diagnosed high-grade glioma decrease recurrence and improve disease-free survival and may seek fast track designation for CAN-3110 or certain of our future product candidates. However, there is no assurance that the FDA will grant this status to CAN-3110 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 or if we do receive fast track designation for CAN-3110 or any other of our future product candidates, 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 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.

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. 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 of that the product's accelerated approval will eventually be converted to a traditional FDA 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, or 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 operations in our new facility and commercial scale manufacturing at third-party manufacturers. 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. 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. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to the COVID-19 pandemic, since March, 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Additionally, as of May 26, 2021, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required, and due to the COVID-19 pandemic and related travel restrictions, the FDA is unable to complete such required inspections during the review period. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and that a remote interactive evaluation is not adequate, the FDA has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to

complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

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, or cGMP, requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and good clinical practices, or 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 CMOs, 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, or 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 lead 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 manufacturing delays or other delays with IND-enabling studies, including due to the impact of the COVID-19 pandemic on suppliers, study sites or third-party contractors and vendors on whom we depend. We may also 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, or collectively, the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or 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. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once 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.

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. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

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.

Our ability to successfully launch and secure market acceptance of our late-stage pipeline candidate, CAN-2409 (if approved), may be impacted by the evolving COVID-19 pandemic, although we are currently unable to predict or quantify any such potential impact with any degree of certainty. If the spread of COVID-19 and the social distancing measures taken by various governments continue, any commercial launch we may undertake may be hindered by various factors, including challenges in hiring the employees necessary to support commercialization; delays in demand due to impacts on the healthcare system and overall economy; delays in coverage decisions from Medicare and third-party payors; restrictions on our personal interactions with physicians, hospitals, payors, and other customers; interruptions or delays in our commercial supply chain; and increases in the number of uninsured or underinsured patients.

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 lead 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 beyond the net proceeds of the IPO 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.

The EU General Data Protection Regulation, or GDPR, also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. The GDPR imposes additional obligations and risk upon our business and substantially increase the penalties to which we could be subject in the event of any non-compliance, including fines of up to €20 million or 4% of total worldwide annual turnover, whichever is higher. Further to the UK's exit from the European Union on January 31, 2020, the GDPR ceased to apply in the UK at the end of the

transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law (referred to as the 'UK GDPR'). The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. In this document, "GDPR" refers to both the EU and the UK GDPR, unless specified otherwise. Given the breadth and depth of changes in data protection obligations, preparing for and complying with the GDPR requirements has required and will continue to require significant time, resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the EEA.

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, or 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 gcomprehensive 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, or 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

The ongoing COVID-19 pandemic 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, this pandemic has caused 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.

The ongoing COVID-19 pandemic has caused many governments to implement measures to slow the spread of COVID-19 through quarantines, travel restrictions, heightened border scrutiny and other measures. The ongoing COVID-19 pandemic and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the COVID-19 pandemic and its effects on our business and operations are uncertain.

The extent to which COVID-19 has had and may continue to have an impact on our operations or those of the third parties on which we rely will depend on many factors, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, any future variants of COVID-19, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19, and the actions to contain the COVID-19 pandemic or address its impact in the short and long term. Additionally, the conduct of our clinical trials, preclinical studies and manufacturing activities is dependent upon the availability of clinical trial sites, CROs, CMOs, researchers and investigators, regulatory agency personnel and logistics providers, all of which may be adversely affected by the ongoing COVID-19 pandemic.

Any negative impact that the ongoing COVID-19 pandemic has 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.

We cannot provide assurance that some factors from the ongoing COVID-19 pandemic will not further delay or otherwise adversely affect our clinical development, research, manufacturing and business operations activities, as well as our business generally, in the future.

We and the third-party manufacturers, CROs and academic collaborators that we engage have faced in the past and may face in the future disruptions that could affect our ability to initiate and complete preclinical studies or clinical trials, including disruptions in procuring items that are essential for our research and development activities, such as, for example, raw materials used in the manufacture of our product candidates, laboratory supplies for our preclinical studies and clinical trials, or animals that are used for preclinical testing, in each case, for which there may be shortages because of ongoing efforts to address the COVID-19 pandemic. For example, during the ongoing COVID-19, global supply chain disruptions have been seen, particularly with raw materials and supplies used in biopharmaceutical production. Three vaccines for COVID-19 have been granted Emergency Use Authorization by the FDA, and more may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. Additionally, the response to the ongoing COVID-19 pandemic may redirect resources with respect to regulatory and intellectual property matters in a way that would adversely impact our ability to pursue marketing approvals and protect our intellectual property. In addition, we may face impediments to regulatory meetings and potential approvals due to measures intended to limit in-person interactions.

In response to the ongoing COVID-19 pandemic and in accordance with direction from state and local governmental authorities, we have been carefully monitoring the ongoing COVID-19 pandemic and its impact on our business and have taken important steps to help ensure the safety of our employees and their families and to reduce the spread of COVID-19. We have established a flexible work policy for our employees under which we encourage all of our employees to work from the office or from home as they feel appropriate. Those employees performing or supporting business-critical operations, such as members of our laboratory and facilities staff, are working on site at our facilities on a daily basis. For those employees who come to work at our facilities, we have implemented stringent safety measures designed to comply with applicable federal, state and local guidelines instituted in response to the COVID-19 pandemic. We have taken these precautionary steps while maintaining business continuity so that we can continue to progress our programs. In the event that governmental authorities were to impose new restrictions, our employees conducting research and development activities may not be able to access our laboratory space, and our core research activities may be significantly limited or curtailed, possibly for an extended period of time.

The COVID-19 pandemic continues to rapidly evolve, and its ultimate scope, duration and effects are unknown. The extent of the impact of the disruptions to our business, preclinical studies and clinical trials as a result of the ongoing COVID-19 pandemic will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the COVID-19 pandemic, travel restrictions and actions to contain the COVID-19 pandemic, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The COVID-19 pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, 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 the pandemic will significantly impact economies worldwide, which could result in adverse effects on our business and operations. We cannot be certain what the overall impact of the ongoing COVID-19 pandemic will be on our business and it has the potential to adversely affect our business, financial condition, results of operations and prospects.

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.

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 to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical, regulatory affairs 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 breaches, 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 breach 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.

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. 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.

We and our independent registered public accounting firm have identified material weaknesses in our internal control over financial reporting in conjunction with their audits of our financial statements for the years ended December 31, 2021 and 2020. If we are unable to remediate these material weakness, or if we identify additional material weaknesses 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.

In preparation of our consolidated financial statements, we and our independent registered public accounting firm identified material weaknesses in 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.

The material weaknesses identified related to:

(1) the fact that we did not have sufficient finance and accounting staff with U.S. generally accepted accounting principles (GAAP) technical and accounting expertise to evaluate and account for significant transactions and oversee our third-party consultants. As a result we did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose certain complex transactions, which led to inappropriate accounting conclusions associated with stock compensation expenses; and

(2) the fact that we lacked proper monitoring entity level controls and segregation of duties due to our small accounting staff.

We have implemented, and are continuing to implement, measures designed to improve internal control over financial reporting to remediate the control deficiencies that led to the material weaknesses, including the following:

- hiring an experienced Chief Financial Officer with experience serving as acting chief financial officer of a public company and serving as an audit partner at a major accounting firm and a controller with experience working at a public company and as a manager at a major public accounting firm;
- strengthening supervisory reviews by our financial management, and
- expanding our accounting and finance team to add additional qualified accounting and finance resources, which may include augmenting our finance team with third-party consultants that possess the required expertise to assist management with their review.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to the material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. In addition, neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses in the future, or 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. In addition to the material weaknesses described above, other 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, or 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, or 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.

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.

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

Recent changes in tax law may adversely affect our business or financial condition. On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act, or TCJA, which significantly reformed the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contains significant changes to corporate taxation, including reducing the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limiting the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), limiting the deduction for NOLs arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of NOL carrybacks for losses arising

in taxable years ending after December 31, 2017 (though any such NOLs may be carried forward indefinitely), imposing a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, eliminating U.S. tax on foreign earnings (subject to certain important exceptions), allowing immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits.

As part of Congress's response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or FFCR Act, was enacted on March 18, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was enacted on March 27, 2020, and COVID relief provisions were included in the Consolidated Appropriations Act, 2021 or CAA, which was enacted on December 27, 2020. Both contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of NOLs, which was enacted as part of the TCJA. It also provides that NOLs arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income.

Regulatory guidance under the TCJA, the FFCR Act, the CARES Act and the CAA is and continues to be forthcoming, and such guidance could ultimately increase or lessen their impact on our business and financial condition. It is also likely that Congress will enact additional legislation in connection with the COVID-19 pandemic, some of which could have an impact on us. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act, the Cares Act, or the CAA. 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 Internal Revenue Code of 1986, as amended, 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 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, 2021, we had U.S. federal and state net operating loss carryforwards of $8.8 million and $48.4 million, which begin to expire in 2027 and 2032, respectively. As of December 31, 2020, we had U.S. federal and state net operating loss carryforwards of $8.8 million and $27.6 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 the TCJA may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under the TCJA, 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 the TCJA, the amount of post-2017 net operating losses 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, 2021, we had a U.S. federal net operating loss carryforward of $42.8 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.

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.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a negative effect on our business, financial condition, results of operations, stock price and prospects.

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.

There may also be delays in obtaining coverage and reimbursement for newly approved therapeutics, and coverage may be more limited than the indications for which the product is approved by the FDA or comparable foreign regulatory authorities. Such delays have made it increasingly common for manufacturers to provide newly approved drugs to patients experiencing coverage delays or disruption at no cost for a limited period in order to ensure that patients are able to access the drug. Moreover, eligibility for reimbursement does not imply that any therapeutic will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new therapeutics, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost products or may be incorporated into existing payments for other services.

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.

We are subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators and raise capital.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may

result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products.

In particular, in 2010, the ACA was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed on procedural grounds the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an Executive Order that initiated a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

Legislative changes have been proposed and adopted since the ACA was enacted in 2010. These changes include, among other things, aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went effective on April 1, 2013, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. Pursuant to the CARES Act, as well as subsequent legislation, these reductions were suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Following the temporary suspension, a 1% payment reduction began on April 1, 2022 that lasted through June 30, 2022, and the 2% payment reduction resumed on July 1, 2022. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

President Biden signed an Executive Order on July 9, 2021, affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. The FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Further, on November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. On December 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction against implementation of the interim final rule. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Model interim final rule shall not commence earlier than sixty (60) days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for

certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026.

In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the fiscal year 2019 and 2018 reimbursement formula on specified covered outpatient drugs (SCODs). The court ruled this change was not an “adjustment” which was within the Secretary’s discretion to make but was instead a fundamental change in the reimbursement calculation. However, most recently, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court’s decision and found that the changes were within the Secretary’s authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA, as well as other federal and state healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our biopharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government healthcare 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 commercializing our products and being able to generate revenue, and we could be prevented from or significantly delayed in achieving profitability.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the biopharmaceutical industry. For instance, the Drug Quality and Security Act imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the product to individuals and entities to which product ownership is transferred, will be required to label products with a product identifier, and are required keep certain records regarding the product. The transfer of information to subsequent product owners by manufacturers is also required to be done electronically. Manufacturers are also being required to verify that purchasers of the manufacturers’ products are appropriately licensed. Further, manufacturers have product investigation, quarantine, disposition, and FDA, other comparable foreign regulatory authorities, and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences of death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Compliance with the federal track and trace requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Our employees, independent contractors, consultants, commercial partners, principal investigators, CROs or CMOs 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, CMOs 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.

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 have entered into a collaboration with Bristol-Myers Squibb Company, or BMS, and the Adult Brain Tumor Consortium, or ABTC, for a Phase 1b clinical trial in high-grade glioma patients. 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 at our facility in Needham, Massachusetts for our product candidate CAN-3110 and we may also develop clinical scale manufacturing 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 CMOs 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 the COVID-19 pandemic, 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 CMOs 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.

CMOs 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 CMOs 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 FDA approval for the use of any new manufacturers for commercial supply.

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-initiated 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-initiated clinical trials. Investigator-initiated 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-initiated 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-initiated 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, or 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 July 31, 2022, Estuardo Aguilar-Cordova and Laura Aguilar beneficially owned 6,216,971 shares of our common stock, or approximately 21.5% 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 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.

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, or 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.

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 heavily 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 clinical development strategy includes the testing of live tissue samples, and our techniques for preserving and testing these samples 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 clinical 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 proceedings. 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, or 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.

Any patents, if issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

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 patent relating to our CAN-2409 product candidate that expires in 2034, and our in-licensed 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 2042, 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.

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.

In addition, the trading prices for our and other biopharmaceutical companies’ stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak further impacts our business, including our preclinical studies and clinical trials, results of operations and financial condition will depend on future developments which are highly uncertain and cannot be predicted with confidence. Such factors include, but are not limited to, the duration of the outbreak, the impact of variants, travel restrictions, quarantines, shelter-in-place orders and social distancing, business closures or business disruptions, the adoption and effectiveness of vaccines and vaccine distribution efforts, and the effectiveness of other actions taken in the United States and other countries to contain and treat the disease.

Raising additional capital through the sale of a substantial number of shares of our common stock, or the perception that substantial sales might occur, may cause dilution to our stockholders and 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. 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, or 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, or 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 $1.07 billion or more; (ii) December 26, 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 Sarbanes-Oxley Act of 2002, or 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 shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this Quarterly Report on Form 10-Q. In particular, we have not included 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 Securities Exchange Act of 1934, as amended, or 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 Sarbanes-Oxley Act of 2002 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, or 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 July 31, 2022, we have outstanding a total of 28,891,909 shares of common stock.

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 of 1933, as amended, or 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.

The holders of 8,884,661 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 59.7% of our outstanding common stock with Estuardo Aguilar-Cordova and

Laura Aguilar (together, both directly and indirectly) beneficially owning approximately 21.5% of our outstanding common stock, and with entities and persons affiliated with PBM Capital beneficially owning approximately 29.2% of our outstanding common stock. In addition, Diem Nguyen, who is a member of our Board of Directors, is currently Chief Executive Officer of Xalud Therapeutics, Inc., which is majority-owned by PBM Capital. 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 have been highly volatile as a result of the COVID-19 pandemic. 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 preferred stock, we issued warrants to purchase 3,672,484 shares of common stock for $6.81 per share to a purchaser of our Series B preferred stock which were immediately and remain fully exercisable upon issuance, or the Unconditional Series B Warrants. We also issued warrants for the purchase of up to an additional 3,672,484 shares of common for $6.81 per share, or the Conditional Series B Warrants. As amended on July 14, 2021, each of the Unconditional Series B Warrants and Conditional Series B Warrants expire in November 2025. The Conditional Series B Warrants are only exercisable in the event that we achieve certain financial conditions 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, or a Financing Event, 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. The Unconditional Series B Warrants contain provisions allowing for cash and on a cashless exercise basis. The Conditional Series B Warrants are only exercisable in connection with the first to occur of (i) a sale of the Company, which did not result from the consummation of the IPO, or (ii) the Conditional Series B Warrants' expiration in November 2025. The Conditional Series B Warrants contain provisions allowing for cash and on a cashless exercise basis in connection with a sale event, and only on a cashless exercise basis in connection with the Conditional Series B Warrants' expiration in November 2025. 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.

On July 29, 2021, we issued and sold 9,000,000 shares of our common stock in the IPO, at a public offering price of $8.00 per share, and on August 13, 2021, we issued and sold an additional 887,994 shares of our common stock pursuant to the exercise in part by the underwriters of their over-allotment option to purchase additional shares at the same public offering price.

The offer and sale of all the shares in the IPO, inclusive of the underwriters' exercise in part of their over-allotment option, 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. Jefferies LLC, Credit Suisse Securities (USA) LLC, BMO Capital Markets Corp. and UBS Securities LLC acted as joint book-running managers for the offering. Upon completion of the IPO, inclusive of the underwriters' exercise in part of their over-allotment option, we received approximately $71.3 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by us of approximately $7.6 million. No payments for any expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus, dated July 26, 2021, filed with the SEC pursuant to Rule 424(b) relating to our registration statement on Form S-1 on July 28, 2021.

Item 3. Defaults Upon Senior Securities.

None

Item 4. Mine Safety Disclosures.

Not Applicable

Item 5. Other Information.

None

Item 6. Exhibits.

Furnish the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

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*#	Employment Agreement by and between Candel Therapeutics and Seshu Tyagarajan dated April 14, 2022
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 Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

# Indicates a management contract or any compensatory plan, contract or arrangement.

+ 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: August 5, 2022

By: /s/ Paul Peter Tak
Paul Peter Tak
President and Chief Executive Officer

Date: August 5, 2022

By: /s/ John Canepa
John Canepa
Chief Financial Officer
(Principal financial officer and principal accounting officer)

EMPLOYMENT AGREEEMENT

This Employment Agreement ("Agreement") is made between Candel Therapeutics, Inc., a Delaware corporation (the "Company"), and Seshu Tyagarajan (the "Executive") and is made effective as of April 14, 2022 or a mutually agreeable start date.

WHEREAS, the Company desires to employ the Executive and the Executive desires to be employed by the Company on the terms and conditions contained herein: and

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

1. Employment.

(a) Term. The Company shall employ the Executive and the Executive shall be employed by the Company pursuant to this Agreement commencing as of the Effective Date and continuing until such employment is terminated in accordance with the provisions hereof (the "Term"). The Executive's employment with the Company shall continue to be "at will," meaning that the Executive's employment may be terminated by the Company or the Executive at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. The Executive shall serve as the Chief Technical and Development Officer of the Company and will report to the Chief Executive Officer. The Executive shall devote the Executive's full working time and efforts to the business and affairs of the Company. In your position as Chief Technical and Development Officer, you will be responsible for the following:

- Develop and implement Manufacturing Science, Engineering and Technical Operations strategies for clinical and commercial manufacturing of oncolytic viral therapies.
- Ensure success of all production activities and projects including tech transfer, facility build-out, commissioning, qualification, and facility start-up, process control and stewardship, and life cycle management.
- Responsible for long-range strategic planning and implementation for oncolytic virus clinical and commercial manufacturing, development, and management of Candel's manufacturing, technical and engineering teams to drive the product-specific technology strategy, from development of clinical through commercial manufacturing.
- Lead the manufacturing team in operations, regulatory preparedness planning and client and regulatory agency visits and inspections.
- Lead Contract Manufacturing selection efforts and oversee CMO relationship(s).

- Participate in the evolution of the company's overall business strategy, as an extension of the technical operations strategy.

2. Compensation and Related Matters.

(a) Base Salary. The Executive's initial base salary shall be paid at a rate of **$360,000.00** per year commencing on the Effective Date (April 14, 2022). The Executive's base salary shall be reviewed for increase annually by the CEO and/or Compensation Committee of the Board (the Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for employees.

(b) Incentive Compensation. The Executive shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time. The Executive's initial target annual incentive compensation shall be **35%** of the Executive's Base Salary. The target annual bonus incentive compensation in effect at any given time is referred to herein as "Target Bonus." The actual amount of the Executive's annual incentive compensation, if any, shall be determined by the CEO and the Compensation Committee in their discretion, subject to the terms of any applicable incentive compensation plan that may be in effect from time to time. Except as otherwise provided herein, as may be provided by the CEO or the Compensation Committee or as may otherwise be set forth in the applicable compensation plan, the Executive must be employed by the Company on the day such annual incentive compensation is paid to receive any annual incentive compensation; provided, however, that such annual incentive compensation will be paid no later than March 15th of the following year.

(c) Signing Bonus. The Executive shall be eligible to receive a Signing Bonus in the gross amount of **$20,000**, less applicable taxes and withholdings. This Signing Bonus will be paid within 30 days following the Effective Date. The Executive agrees that should she voluntarily terminate her employment with the company for reasons excluding redundancy or ill health within twelve months of commencement of employment, she will reimburse the company for all Signing Bonus monies paid to her.

(d) Expenses. The Executive shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by the Executive during the Term in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company for its employees.

(e) Other Benefits. The Executive shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(e) Paid Time Off. The Executive shall be entitled to take paid time off in accordance with the Company's applicable paid time off policy as may be in effect from time to time. The Executive shall also be entitled to all paid holidays given by the Company to its executive officers.

(f) Equity. In connection with the commencement of the Executive's employment, the Company will recommend to the Board that Executive be granted an option to purchase **120,000** shares of the Company's common stock, with an exercise price equal to the fair market value of the Company's common stock as of the date of such grant, subject to time-based vesting as follows: 25% shall vest on the first anniversary of your start date at the Company (April 14, 2023), and 1/36 of the total remaining unvested shall vest monthly thereafter over the following 3 years until all are vested in each case subject to Executive's continued employment with the Company on each such vesting date. The equity awards held by the Executive, if approved by the Board, shall be governed by the terms and conditions of the Company's applicable equity incentive plan(s) and the applicable award agreement(s) governing the terms of such equity awards held by the Executive (collectively, the "Equity Documents"); provided, however, and notwithstanding anything to the contrary in the Equity Documents, all stock options and other stock-based awards held by the Executive that are subject solely to time-based vesting (the "Time-Based Equity Awards") shall immediately accelerate and become fully vested and exercisable or nonforfeitable if a Change in Control (to be defined in the Equity Documents) occurs and within one (1) month prior to, or within twelve (12) months after, the effective time of such Change in Control, Executive's employment terminates due to an involuntary termination (not including death or Disability) without Cause (as defined below) or due to Executive's voluntary termination with Good Reason (as defined below).

3. Termination. The Executive's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Executive's employment hereunder shall terminate upon her death.

(b) Disability. The Company may terminate the Executive's employment if the Executive is disabled and unable to perform the essential functions of the Executive's then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any question shall arise as to whether during any period the Executive is disabled so as to be unable to perform the essential functions of the Executive's then existing position or positions with or without reasonable accommodation, the Executive may, and at the request of the Company shall, submit to the Company a certificate in reasonable detail by a physician selected by the Company to whom the Executive or Executive's guardian has no reasonable objections as to whether the Executive is so disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. The Executive shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and the Executive shall fail to submit such certification, the Company's determination of such issue shall be binding on the Executive. Nothing in this Section 3(b) shall be construed to waive the Executive's rights, if any, under existing law

including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 et seq. and the Americans with Disabilities Act, 42 U.S.C. §12101 et seq.

(c) Termination by the Company for Cause. The Company may terminate the Executive's employment hereunder for Cause. For purposes of this Agreement, "Cause' shall mean any of the following, as expressly determined by the Board:

(i) Executive's conviction of any felony or any crime involving fraud or dishonesty;

(ii) Executive's participation in a fraud, act of dishonesty or other act of gross misconduct that adversely affect the Company;

(iii) Conduct by the Executive that demonstrates Executive's gross unfitness to serve;

(iv) Executive's violation of any statutory or fiduciary duty, or duty of loyalty, owed to the Company;

(v) Executive's breach of any material term of any contract between such Executive and the Company; and/or

(vi) Executive's material violation of Company policy.

Whether a termination is for Cause shall be decided by the Board in their exclusive judgement and discretion, exercised in good faith. Prior to any termination for Cause pursuant to each event listed in (iv), (v) and (vi) above, to the extent such event(s) is capable of being cured by the Executive, (A) the Company shall give the Executive notice of such event(s), which notice shall specify in reasonable detail the circumstances constituting Cause, and (B) there shall be no Cause with respect to any such event(s) if the Board determines in good faith that such events have been cured by Executive within fifteen (15) days after the delivery of such notice.

(d) Termination by the Company without Cause. The Company may terminate the Executive's employment hereunder at any time without Cause. Any termination by the Company of the Executive's employment under this Agreement which does not constitute a

termination for Cause under Section 3(c) and does not result from the death or disability of the Executive under Section 3(a) or (b) shall be deemed a termination without Cause.

(e) Termination by the Executive. The Executive may terminate employment hereunder at any time for any reason, including but not limited to, Good Reason by delivery of written notice to the Company effective fifteen (15) days after the date of delivery of such notice. For purposes hereof, "Good Reason" shall mean that the Executive has completed all steps of the Good Reason Process (hereinafter defined) following the occurrence of any of the following events without the Executive's consent (each, a "Good Reason Condition"):

(i) a material reduction by the Company of Executive's Base Salary as initially set forth herein or as the same may be increased from time to time, provided, however, that if such reduction occurs in connection with a Company-wide decrease in executive team compensation, such reduction shall not constitute Good Reason;

(ii) a material breach of this Agreement by the Company;

(iii) the relocation of the Company's principal office, without Executive's consent, in a manner that lengthens his one-way commute distance by twenty-five (25) or more miles from his then-current principal place of employment immediately prior to such relocation; or

(iv) a material reduction in Executive's duties, authority, or responsibilities relative to Executive's duties, authority, or responsibilities in effect immediately prior to such reduction unless Executive is performing duties and responsibilities for the Company or its successor that are similar to those Executive was performing for the Company immediately prior to such transaction.

The "Good Reason Process" consists of the following steps:

(i) the Executive reasonably determines in good faith that a Good Reason Condition has occurred;

(ii) the Executive notifies the Company in writing of the first occurrence of the Good Reason Condition within 30 days of the first occurrence of such condition;

(iii) the Executive cooperates in good faith with the Company's efforts, for a period of not less than 30 days following such notice (the "Cure Period"), to remedy the Good Reason Condition;

(iv) notwithstanding such efforts, the Good Reason Condition continues to exist; and

(v) the Executive terminates employment within 30 days after the end of the Cure Period.

If the Company cures the Good Reason Condition during the Cure Period, Good Reason shall be deemed not to have occurred.

4. Matters Related to Termination.

(a) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Executive's employment by the Company or any such termination by the Executive shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(b) Date of Termination. "Date of Termination" shall mean: (i) if the Executive's employment is terminated by death, the date of death; (ii) if the Executive's employment is terminated on account of disability under Section 3(b) or by the Company for Cause under Section 3(c), the date on which Notice of Termination is given; (iii) if the Executive's employment is terminated by the Company without Cause under Section 3(d), the date on which a Notice of Termination is given or such later date specified by the Company in the Notice of Termination if agreed to by the Executive; (iv) if the Executive's employment is terminated by the Executive under Section 3(e) other than for Good Reason, 30 days after the date on which a Notice of Termination is given, and (v) if the Executive's employment is terminated by the Executive under Section 3(e) for Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that the Executive gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement.

(c) Accrued Obligations. If the Executive's employment with the Company is terminated for any reason, the Company shall pay or provide to the Executive (or to the Executive's authorized representative or estate) (i) any Base Salary earned through the Date of Termination; (ii) unpaid expense reimbursements (subject to, and in accordance with, Section 2(c) of this Agreement); and (iii) any vested benefits the Executive may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Obligations").

(d) Resignation of All Other Positions. To the extent applicable, the Executive shall be deemed to have resigned from all officer and board member positions that the Executive holds with the Company or any of its respective subsidiaries and affiliates upon the termination of the Executive's employment for any reason. The Executive shall execute any documents in reasonable form as may be requested to confirm or effectuate any such resignations.

5. Severance Pay and Benefits Upon Termination by the Company without Cause or by the Executive for Good Reason. If the Executive's employment is terminated by the Company without Cause as provided in Section 3(d), or the Executive terminates employment for Good Reason as provided in Section 3(e), then, in addition to the Accrued Obligations, and subject to (i) the Executive signing a separation agreement and release in a form and manner satisfactory to the Company, which shall include, without limitation, a general release of claims against the Company and all related persons and entities, a reaffirmation of all of the Executive's Continuing Obligations (as defined below), and in the Company's sole discretion, a nine-month post-employment noncompetition agreement, and shall provide that if the Executive breaches any of the Continuing Obligations, all payment of Severance Amount shall immediately cease (the "Separation Agreement and Release"), and (ii) the Separation Agreement and Release becoming irrevocable, all within sixty (60) days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release), which shall include a seven (7) business day revocation period:

(a) the Company shall pay the Executive an amount equal to (A) nine (9) months of the Executive's then-current Base Salary plus (B) the Executive's Target Bonus for the then-current year (the "Severance Amount"); provided that in the event the Executive is entitled to any payments pursuant to the Restrictive Covenants Agreement, the Severance Amount received in any calendar year will be reduced by the amount the Executive is paid in the same such calendar year pursuant to the Restrictive Covenants Agreement (the "Restrictive Covenants Agreement Setoff"); and

(b) subject to the Executive's copayment of premium amounts at the applicable active employees' rate and the Executive's proper election to receive benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company shall pay to the group health plan provider or the COBRA provider a monthly payment equal to the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company until the earliest of (A) the 9 month anniversary of the Date of Termination; (B) the date that the Executive becomes eligible for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of the Executive's health continuation rights under COBRA; provided, however, that if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to the Executive for the time period specified above. Such payments to the Executive shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

The amounts payable under Section 5, to the extent taxable, shall be paid out in substantially equal installments in accordance with the Company's payroll practice over 9 months commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments, to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), shall begin to be paid in

the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

6. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Executive's separation from service within the meaning of Section 409A of the Code, the Company determines that the Executive is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Executive becomes entitled to under this Agreement on account of the Executive's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Executive's separation from service, or (B) the Executive's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Executive during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Executive's termination of employment, then such payments or benefits shall be payable only upon the Executive's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as

reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

7. Continuing Obligations.

(a) Restrictive Covenants Agreements. As a condition of employment, the Executive shall be required to enter into the Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement attached hereto as Exhibit A (the "Restrictive Covenants Agreement"). The Executive acknowledges and agrees that the Executive received the Restrictive Covenants Agreement with this Agreement before the commencement of the Executive's employment. For purposes of this Agreement, the obligations in this Section 7 and those that arise in the Restrictive Covenants Agreement and any other agreement relating to confidentiality, assignment of inventions, or other restrictive covenants shall collectively be referred to as the "Continuing Obligations."

(b) Third-Party Agreements and Rights. The Executive hereby confirms that the Executive is not bound by the terms of any agreement with any previous employer or other party which restricts in any way the Executive's use or disclosure of information, other than confidentiality restrictions (if any), or the Executive's engagement in any business of the Company's. The Executive represents to the Company that the Executive's execution of this Agreement, the Executive's employment with the Company and the performance of the Executive's proposed duties for the Company will not violate any obligations the Executive may have to any such previous employer or other party. In the Executive's work for the Company, the Executive will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and the Executive will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(c) Litigation and Regulatory Cooperation. During and after the Executive's employment, the Executive shall cooperate fully with the Company in (i) the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Executive was employed by the Company, and (ii) the investigation, whether internal or external, of any matters about which the Company believes the Executive may have knowledge or information. The Executive's full cooperation in connection with such claims, actions or investigations shall include, but not be limited to, being available to meet with counsel to answer questions or to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Executive's employment, the Executive also shall cooperate fully with the Company, at mutually convenient times, in connection with any investigation or review of any federal, state or local regulatory authority as any such

investigation or review relates to events or occurrences that transpired while the Executive was employed by the Company. The Company shall reimburse the Executive for any reasonable out of pocket expenses incurred in connection with the Executive's performance of obligations pursuant to this Section 7(c). It is anticipated and intended that the Executive's post-employment cooperation pursuant to this Section 7(c) will not unreasonably interfere with his other employment, business or personal obligations.

(d) Relief. The Executive agrees that it would be difficult to measure any damages caused to the Company which might result from any material breach by the Executive of the Continuing Obligations, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, the Executive agrees that if the Executive materially breaches, or proposes to materially breach, any portion of the Continuing Obligations, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such material breach without showing or proving any actual damage to the Company.

8. Consent to Jurisdiction. The parties hereby consent to the jurisdiction of the state and federal courts of the Commonwealth of Massachusetts. Accordingly, with respect to any such court action, the Executive (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

9. Integration. This Agreement (and the Restrictive Covenants Agreement referenced herein) constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter.

10. Withholding; Tax Effect. All payments made by the Company to the Executive under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law. Nothing in this Agreement shall be construed to require the Company to make any payments to compensate the Executive for any adverse tax effect associated with any payments or benefits or for any deduction or withholding from any payment or benefit.

11. Successors and Assigns. Neither the Executive nor the Company may make any assignment of this Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; provided, however, that the Company may assign its rights and obligations under this Agreement (including the Restrictive Covenants Agreement) without the Executive's consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization or consolidation, into which the Company merges or to whom it transfers all or substantially all of its properties or assets; provided further that if the Executive remains employed or becomes employed by the Company, the purchaser or any of their affiliates in connection with any such transaction, then the Executive shall not be entitled to any payments, benefits or vesting pursuant to Section 5 of this Agreement solely as a result of such transaction. This Agreement shall inure to the benefit of and be binding upon the Executive and the Company, and each of the Executive's and the Company's respective successors, executors, administrators, heirs and permitted assigns. In the event of the Executive's death after the

Executive's termination of employment but prior to the completion by the Company of all payments or other compensation due to the Executive under this Agreement, the Company shall continue such payments and provide such other compensation to the Executive's beneficiary designated in writing to the Company prior to the Executive's death (or to the Executive's estate, if the Executive fails to make such designation).

12. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

13. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Executive's employment to the extent necessary to effectuate the terms contained herein.

14. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

15. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally or internationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Executive at the last address the Executive has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

16. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Executive and by a duly authorized representative of the Company.

17. Effect on Other Plans and Agreements. An election by the Executive to resign for Good Reason under the provisions of this Agreement shall not be deemed a voluntary termination of employment by the Executive for the purpose of interpreting the provisions of any of the Company's benefit plans, programs or policies. Nothing in this Agreement shall be construed to limit the rights of the Executive under the Company's benefit plans, programs or policies except as otherwise provided in Section 7 hereof, and except that the Executive shall have no rights to any severance benefits under any Company severance pay plan, offer letter or otherwise. Except for the Restrictive Covenants Agreement, in the event that the Executive is party to an agreement with the Company providing for payments or benefits under such agreement and this Agreement, the terms of this Agreement shall govern and the Executive may receive payment under this Agreement only and not both.

18. Governing Law. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of laws principles thereof. With respect to any disputes concerning federal law, such disputes shall be determined in accordance with the law as it would be interpreted and applied by the United States Court of Appeals for the First Circuit.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the Effective Date.

COMPANY:

Candel Therapeutics, Inc.

By: _____
Name: Paul Peter Tak
Title: Chief Executive Officer

EXECUTIVE: _____

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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (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: August 5, 2022

By: /s/ Paul Peter Tak

Paul Peter Tak
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS

I, John Canepa, 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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (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: August 5, 2022

By: /s/ John Canepa

John Canepa
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 June 30, 2022 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: August 5, 2022

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 June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Canepa, 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: August 5, 2022

By: /s/ John Canepa

John Canepa
Chief Financial Officer
(principal financial officer and principal accounting officer)