UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2024

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

For the transition period from _____ to _____

GENELUX CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	001-41599	**77-0583529**
(State or other jurisdiction of incorporation or organization)	Commission File Number	(IRS Employee Identification No.)

2625 Townsgate Road, Suite 230, Westlake Village, California 91361
(Address of Principal Executive Offices)

(805) 267-9889
(Registrant's telephone number, including area code)

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

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

Title of each class registered:	**Trading symbol:**	**Name of each exchange on which registered:**
Common Stock, par value $0.001 per share	GNLX	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Securities registered under Section 12(g) of the Exchange Act: None

Indicate by check mark whether the issuer (1) 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or smaller reporting company filer. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act (Check one):

Large Accelerated Filer ☐ Non-Accelerated Filer ☒
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 ☒

The number of shares issued and outstanding of each of the issuer's classes of common equity as of May 5, 2024 was 26,996,740.

GENELUX CORPORATION
FORM 10-Q
MARCH 31, 2024
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Item 1: Financial Statements.

Genelux Corporation
Condensed Balance Sheets
(in thousands, except for share amounts and par value data)

	March 31, 2024 (Unaudited)	December 31, 2023
ASSETS		
Current Assets		
Cash and cash equivalents	$ 4,061	$ 9,418
Short-term investments	15,566	13,773
Prepaid expenses and other current assets	1,577	1,012
Total Current Assets	21,204	24,203
Property and equipment, net	1,116	1,170
Right of use assets	2,264	2,428
Other assets	92	92
Total Other Assets	3,472	3,690
TOTAL ASSETS	$ 24,676	$ 27,893
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities		
Accounts payable and accrued expenses	$ 5,313	$ 3,784
Accrued payroll and payroll taxes	1,908	2,117
Lease liabilities, current portion	584	653
Total Current Liabilities	7,805	6,554
Lease liabilities, long-term portion	1,787	1,866
Total Liabilities	9,592	8,420
Shareholders' Equity		
Preferred stock, par value $0.001, 10,000,000 shares authorized; no shares issued and outstanding, respectively;	-	-
Common stock, par value $0.001, 200,000,000 shares authorized; 26,996,740 and 26,788,986 shares issued and outstanding, respectively	27	27
Treasury stock, 433,333 shares, at cost	(433)	(433)
Additional paid-in capital	244,869	241,389
Accumulated other comprehensive income (loss)	(5)	14
Accumulated deficit	(229,374)	(221,524)
Total Shareholders' Equity	15,084	19,473
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 24,676	$ 27,893

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

Genelux Corporation
Condensed Statements of Operations
(in thousands, except for share amounts and per share data)

	Three Months Ended March 31,	
	2024	**2023**
	(Unaudited)	
Revenues	$ 8	$ 170
Operating expenses:		
Research and development	4,010	2,845
General and administrative	4,113	3,787
Total operating expenses	8,123	6,632
Loss from operations	(8,115)	(6,462)
Other income (expenses):		
Interest income	265	-
Interest expense	-	(143)
Debt discount amortization	-	(649)
Financing costs	-	(3,110)
Total other income (expenses), net	265	(3,902)
NET LOSS	$ (7,850)	$ (10,364)
LOSS PER COMMON SHARE - BASIC AND DILUTED	$ (0.29)	$ (0.53)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING - BASIC AND DILUTED	26,849,737	19,575,631

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

Genelux Corporation
Condensed Statements of Comprehensive Loss
(in thousands)

	Three Months Ended March 31,	
	2024	**2023**
	(Unaudited)	
Net loss	$ (7,850)	$ (10,364)
Other comprehensive loss:		
Net unrealized loss on short-term investments	(19)	-
Comprehensive loss	$ (7,869)	$ (10,364)

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

Genelux Corporation
Condensed Statements of Shareholders' Equity (Unaudited)
(in thousands, except share amounts)

	Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Total
Balance, December 31, 2022	22,094,889	$ 22	9,126,726	$ 9	(433,333)	$ (433)	$ 154,401	$ 2	$ (189,784)	$ (35,783)
Stock compensation	-	-	-	-	-	-	227	-	-	227
Issuance of common shares upon the closing of the initial public offering, net of offering costs	-	-	2,653,000	3	-	-	12,629	-	-	12,632
Issuance of common shares upon conversion of preferred stock	(22,094,889)	(22)	8,355,610	8	-	-	14	-	-	-
Issuance of common shares upon conversion of convertible notes payable, accrued interest and loan fees	-	-	4,134,367	5	-	-	29,891	-	-	29,896
Issuance of common shares upon conversion of preferred stock dividends payable	-		272,101	-	-	-	3,443	-	(3,443)	-
Fair value of vested restricted stock units	-	-	-	-	-	-	198	-	-	198
Cost of stock option repricing	-	-	-	-	-	-	2,606	-	-	2,606
Reclassification of warrant liabilities upon the closing of the initial public offering	-	-	-	-	-	-	169	-	-	169
Fair value of warrants issued in connection with the the conversion of convertible notes payable	-	-	-	-	-	-	3,110	-	-	3,110
Shares issued upon cashless exercise of stock warrant	-	-	11,666	-	-	-	-	-	-	-
Net loss during the three months ended March 31, 2023	-	-	-	-	-	-	-	-	(10,364)	(10,364)
Balance, March 31, 2023 (unaudited)	-	$ -	24,553,470	$ 25	(433,333)	$ (433)	$ 206,688	$ 2	$ (203,591)	$ 2,691
Balance, December 31, 2023	-	$ -	26,788,986	$ 27	(433,333)	$ (433)	$ 241,389	$ 14	$ (221,524)	$ 19,473
Stock compensation	-	-	-	-	-	-	1,489	-	-	1,489
Unrealized loss on short-term investments	-	-	-	-	-	-	-	(19)	-	(19)
Fair value of vested restricted stock units	-	-	131,267	-	-	-	989	-	-	989
Cost of stock option modifications and repricing	-	-	-	-	-	-	314	-	-	314
Issuance of common shares upon exercise of stock warrants	-	-	76,487	-	-	-	688	-	-	688
Net loss during the three months ended March 31, 2024	-	-	-	-	-	-	-	-	(7,850)	(7,850)
Balance, March 31, 2024 (unaudited)	-	$ -	26,996,740	$ 27	(433,333)	$ (433)	$ 244,869	$ (5)	$ (229,374)	$ 15,084

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

Genelux Corporation
Condensed Statements of Cash Flows
(in thousands)

	Three Months Ended March 31,	
	2024	**2023**
	(Unaudited)	
Cash Flows from Operating Activities		
Net loss	$ (7,850)	$ (10,364)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	84	136
Net amortization of premiums and discounts on short-term investments	(151)	-
Right-of-use assets	164	118
Amortization of debt discount	-	649
Stock compensation	1,489	227
Fair value of restricted stock units	989	198
Cost of stock option modifications and repricing	314	2,606
Fair value of warrants issued in connection with the conversion of convertible notes payable	-	3,110
Changes in Assets and Liabilities		
(Increase) Decrease in:		
Prepaid expenses and other assets	(565)	(223)
(Decrease) Increase in:		
Accounts payable and accrued expenses	1,529	(913)
Accrued payroll and payroll taxes	(209)	58
Accrued interest payable	-	92
Deferred revenue	-	(170)
Lease liability	(148)	(114)
Net cash used in operating activities	(4,354)	(4,590)
Cash Flows from Investing Activities		
Purchases of property and equipment	(30)	(109)
Purchase of short-term investments	(3,161)	-
Proceeds from sales and maturities of short-term investments	1,500	-
Net cash used in investing activities	(1,691)	(109)
Cash Flows from Financing Activities		
Proceeds from notes payable - shareholders	-	900
Repayment of notes payable - shareholders	-	(460)
Payment of deferred offering costs	-	(303)
Proceeds from the exercise of stock warrants	688	-
Proceeds from common stock issued for cash in connection with the closing of the IPO	-	14,503
Net cash provided by financing activities	688	14,640
Net increase (decrease) in cash and cash equivalents	(5,357)	9,941
Cash and cash equivalents at beginning of period	9,418	397
Cash and cash equivalents at end of period	$ 4,061	$ 10,338
Supplemental cash flows disclosures:		
Interest paid	$ -	$ 50
Taxes paid	$ -	$ -
Supplemental non-cash financing disclosures:		
Effect of the extension of right-of-use assets and operating leases	$ -	$ 649
Reclassification of deferred offering costs to shareholders' equity	$ -	$ 1,871
Reclassification of warrant liabilities to shareholders' equity	$ -	$ 169
Conversion of convertible notes payable, accrued interest and loan fees to shareholders' equity	$ -	$ 29,896
Conversion of preferred stock to common stock	$ -	$ 22
Conversion of dividends payable to shareholders' equity	$ -	$ 3,443
Conversion of notes payable-shareholders and accrued interest to shareholders' equity	$ -	$ -

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

NOTE 1 – BASIS OF PRESENTATION

Organization and Operations

Genelux Corporation ("Genelux" or the "Company"), a Delaware Corporation, incorporated on September 4, 2001, is a late clinical-stage biopharmaceutical company located in Westlake Village, California. The Company is engaged in the research and development of diagnostic and therapeutic solutions for cancer for which there is no effective treatment today. The Company is focused on developing a pipeline of next-generation oncolytic viral immunotherapies for patients suffering from aggressive and/or difficult-to-treat solid tumor types.

Basis of Presentation of Unaudited Financial Information

The accompanying unaudited condensed financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all normal recurring adjustments considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024.

Going Concern

The accompanying condensed financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As reflected in the accompanying financial statements, the Company has experienced recurring losses from operations since inception and incurred a net loss of $7,850 and used cash in operations of $4,354 during the three months ended March 31, 2024, and had an accumulated deficit of $229,374 as of March 31, 2024. These factors raise substantial doubt about the Company's ability to continue as a going concern. The ability of the Company to continue as a going concern is dependent upon the Company's ability to raise additional funds and implement its strategies. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

At March 31, 2024, the Company had cash and cash equivalents, and short-term investments, in the amount of $19,627. The ability to continue as a going concern is dependent on the Company attaining and maintaining profitable operations in the future and raising additional capital to meet its obligations and repay its liabilities arising from normal business operations when they come due. Since inception, the Company has funded its operations primarily through equity and debt financings, and licensing income, and it expects to continue to rely on these sources of capital in the future.

No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to the Company. Even if the Company is able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in case of equity financing, or grant unfavorable terms in future licensing agreements.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the financial statement date and reported amounts of revenue and expenses during the reporting period. Significant estimates are used in the valuation of accruals for potential liabilities, valuations of stock-based compensation, and realization of deferred tax assets, among others. Actual results could differ from these estimates.

Income (Loss) Per Share

Basic loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of outstanding common shares during the period. Diluted loss per share is computed by dividing the net loss applicable to common stockholders by the weighted average number of common shares outstanding plus the number of additional common shares that would have been outstanding if all dilutive potential common shares had been issued.

For the three months ended March 31, 2024 and 2023, the basic and diluted shares outstanding were the same, as potentially dilutive shares were considered anti-dilutive.

The potentially dilutive securities consisted of the following:

	March 31, 2024	March 31, 2023
Stock options	5,118,920	4,201,019
Stock warrants	397,975	1,034,979
Restricted stock units	57,323	113,500
Stock warrants, issuable upon conversion of notes payable	-	69,893
Total	5,574,218	5,419,391

Revenue Recognition

The Company records revenue under the guidance of Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers (Topic 606)* which requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services.

The Company determines revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, the Company satisfies a performance obligation.

Under certain of the Company's licensing, supply and collaboration agreements, it is entitled to receive payment upon the achievement of contingent milestone events or the performance of obligations. The Company recognizes revenue based on guidance in ASC 606. In evaluating revenue recognition under a license agreement, the Company uses a two-step process for determining whether a promised good or service (including a license of intellectual property) is distinct and, therefore, is a performance obligation: (1) consideration of the individual good or service (i.e., whether the good or service is capable of being distinct); and (2) consideration of whether the good or service is separately identifiable from other promises in the contract (i.e., whether the promise to transfer the good or service is distinct in the context of the contract). Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue on the Company's balance sheet. Amounts expected to be recognized as revenue in the next 12 months following the balance sheet date are classified as current liabilities.

During the three months ended March 31, 2024, the Company recognized revenue of $8 relating to its license agreement with ELIAS Animal Health, LLC.

Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at date of purchase to be cash equivalents. Cash equivalents consisted of money market funds as of March 31, 2024 and December 31, 2023. As of March 31, 2024 and December 31, 2023, the amount of cash equivalents included in cash and cash equivalents totaled $2,988 and $7,924, respectively.

Short-Term Investments

The Company's short-term debt security investments are classified as available-for-sale and are carried at fair value, with the unrealized gains and non-credit related losses reported as a component of accumulated other comprehensive loss and included in stockholders' equity. Realized gains and losses and declines in value determined to be other than temporary are based on the specific identification method and are included as a component of total other income (expense), net in the Statements of Operations. There were no realized gains or losses during the three months ended March 31, 2024.

For available-for-sale securities in an unrealized loss position, the Company first assesses whether it intends to sell, or if it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through a charge to interest income. For available-for-sale securities that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers such factors as, among other things, the severity of the impairment, any changes in interest rates, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the short-term debt security investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest income through an allowance account. Any impairment that has not been recorded through an allowance for credit losses is included in other comprehensive loss on the statements of operations and comprehensive loss.

No credit-related losses or impairments have been recognized on the Company's investments in available-for-sale securities during the three months ended March 31, 2024.

All of the Company's short-term investments as of March 31, 2024 had maturities of less than one year.

Fair Value of Financial Instruments

The Company determines the fair value of its assets and liabilities based on the exchange price in U.S. dollars 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 maximize the use of observable inputs and minimize the use of unobservable inputs. The Company uses a fair value hierarchy with three levels of inputs, of which the first two are considered observable and the last unobservable, to measure fair value:

- *Level 1* — Quoted prices in active markets for identical assets or liabilities.
- *Level 2* — Inputs, other than Level 1, that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- *Level 3* — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's short-term investments and cash equivalents are carried at fair value, determined according to the fair value hierarchy described in Note 3 below. The carrying amounts of financial instruments such as cash, short-term investments, and accounts payable and accrued liabilities, approximate the related fair values due to the short-term maturities of these instruments.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted based on the fair value of the award on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company has elected to recognize forfeitures as they occur. The reversal of compensation cost previously recognized for an award that is forfeited because of a failure to satisfy a service or performance condition is recognized in the period of the forfeiture. Generally, the Company issues stock options with only service-based vesting conditions and records the expense for these awards using the straight-line method over the requisite service period.

The Company classifies stock-based compensation expense in its statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The Company was a private company until the completion of its IPO on January 30, 2023. In 2022 and prior, the Company estimated the fair value of common stock using an appropriate valuation methodology, 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. 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, guideline public company information, the prices at which the Company sold its common stock to third parties in arms' length transactions, the rights and preferences of securities senior to the Company's common stock at the time, and the likelihood of achieving a liquidity event such as an initial public offering or sale. Significant changes to the assumptions used in the valuations could result in different fair values of stock options at each valuation date, as applicable.

The fair value of each stock option grant is estimated using the Black-Scholes option-pricing model. The Company was a private company and lacked company-specific historical and implied volatility information. Therefore, it estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies within the biotechnology industry with characteristics similar to the Company. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero, based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with shareholders. For the three months ended March 31, 2024, comprehensive loss included $19 of unrealized losses on short-term investments, net of tax.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosure, which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expense categories that are regularly provided to the chief operating decision maker and included in each reported measure of a segment's profit or loss. The update also requires all annual disclosures about a reportable segment's profit or loss and assets to be provided in interim periods and for entities with a single reportable segment to provide all the disclosures required by ASC 280, Segment Reporting, including the significant segment expense disclosures. The Company adopted ASU 2023-07 beginning January 1, 2024. The Company does not believe the impact of the new guidance and related codification improvements had a material impact to its financial position, results of operations and cash flows.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statements.

NOTE 3 - FAIR VALUE OF FINANCIAL ASSETS AND LIABILITIES

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis:

	Fair Value Measurements as of March 31, 2024, Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 2,988	$ —	$ —	$ 2,988
Short-term investments:				
U.S. Government Agency bonds	—	7,936	—	7,936
U.S. Treasury bonds	—	7,630	—	7,630
	$ 2,988	$ 15,566	$ —	$ 18,554

The underlying securities in the money market funds held by the Company are all government backed securities.

Valuation of cash equivalents and short-term investments

Cash equivalents consisted of money market funds at March 31, 2024. Money market funds were valued by the Company using quoted prices in active markets for identical securities, which represent a Level 1 measurement within the fair value hierarchy. U.S. Government Agency bonds and U.S. Treasury bonds are government backed securities representing a Level 2 measurement within the fair value hierarchy.

NOTE 4 - SHORT-TERM INVESTMENTS

As of March 31, 2024, the Company's available-for-sale investments by type, consisted of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
U.S. Government Agency bonds	$ 7,940	$ —	$ (4)	$ —	$ 7,936
U.S. Treasury bonds	7,633	—	(3)	—	7,630
	$ 15,573	$ —	$ (7)	$ —	$ 15,566

As of March 31, 2024, all available-for-sale securities consisted of investments that mature within one year.

NOTE 5 - PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at March 31, 2024 and December 31, 2023:

	March 31, 2024	December 31, 2023
Furniture and office equipment	$ 148	$ 148
Laboratory equipment	2,819	2,792
Computer equipment	127	127
Leasehold improvements	557	557
Construction-in-progress	998	995
	4,649	4,619
Less: accumulated depreciation and amortization	(3,533)	(3,449)
Property and equipment, net	$ 1,116	$ 1,170

Depreciation expense for the three months ended March 31, 2024 and 2023 was $84 and $136, respectively.

During the year ended December 31, 2023, the Company expended $995 on facility design services relating to future planned construction on its manufacturing facility. During the three months ended March 31, 2024, the Company expended an additional $3 on design services. The Company has accounted for the expenditures as construction-in-progress as of March 31, 2024 and December 31, 2023, and no depreciation will be recorded on these expenditures until the facility has been placed in service. The Company's plan to complete the design phase and begin construction on the facility will be based on available financial resources.

NOTE 6 – ACCRUED PAYROLL AND PAYROLL TAXES

As of December 31, 2023, a total of $2,117 was owed to the Company's Chief Executive Officer and another employee for past due balances that had accrued over a several year period, and for current accrued payroll and payroll taxes, and other compensation related benefits, including payroll tax liabilities of $321 relating to stock option exercises and restricted stock unit vesting. During the three months ended March 31, 2024, the Company did not repay any of the past due accrued amounts owed to the employees, but did repay the $321 owed for payroll tax liabilities. As of March 31, 2024, a total of $1,908 was owed to employees for these past due balances, and for current accrued payroll and payroll taxes, and other compensation related benefits. Subsequent to March 31, 2024, the Company repaid $1,024 of the past due accrued amounts owed to employees.

NOTE 7 – LEASE LIABILITIES

Operating Leases

The Company accounts for leases in accordance with ASC 842, which requires a lessee to record a right-of-use asset and a corresponding lease liability at the inception of the lease initially measured at the present value of the lease payments. In July 2018, the Company entered into a long-term non-cancellable lease agreement for its manufacturing facility that requires aggregate average monthly payments of $10 beginning October 2018. The lease terminated in September 2023, with a Company option to extend for an additional five years. The Company classified the lease as an operating lease and determined that the value of the right of use asset and lease liability at the adoption date was $518 and $519, respectively, using a discount rate of 4.00%. Effective April 2022, the Company extended the lease for the additional five-year period, through September 2028, with no changes to any of the other terms of the lease and has the option to extend the lease for an additional five years. Prior to the extension, the remaining lease liability amounted to $174. On the date of the extension, the Company determined that the value of the new right of use asset and lease liability was $860, respectively, using a discount rate of 4.00%. As such, the Company recorded an increase in lease liability of $686 as a result of the lease extension. Effective July 2023, the Company extended the lease for an additional two-year period, through October 2030, with no changes to any of the other terms of the lease and has the option to extend the lease for an additional five years. Prior to the extension through October 2030, the remaining lease liability amounted to $701. On the date of the extension, the Company determined that the value of the new right of use asset and lease liability was $909, respectively, using a discount rate of 7.00%. As such, the Company recorded an increase in the lease liability of $208 as a result of the lease extension.

In December 2020, the Company entered into a long-term non-cancellable lease agreement for a laboratory facility that requires aggregate average monthly payments of $18 beginning January 2021. The Company classified the lease as an operating lease and determined that the value of the right of use asset and lease liability at the adoption date was $439, respectively, using a discount rate of 4.00%. Effective February 2023, the Company extended the lease through December 2024, with no changes to any of the other terms of the lease.

The average monthly rent payment on the extended lease is approximately $30 per month. Prior to the extension, the remaining lease liability amounted to $12. On the date of the extension, the Company determined that the value of the new right of use asset and lease liability was $649, respectively, using a discount rate of 5.5%. As such, the Company recorded an increase in the lease liability of $637 as a result of the lease extension.

In July 2021, the Company entered into a long-term non-cancellable lease agreement for its new corporate headquarters that requires aggregate average monthly payments of $10 beginning August 2021. The lease terminates in July 2027. The Company classified the lease as an operating lease and determined that the value of the right of use asset and lease liability at the adoption date was $656, respectively, using a discount rate of 4.00%.

In November 2023, the Company entered into a long-term non-cancellable lease agreement for a second manufacturing facility that requires aggregate average monthly payments of $12 beginning November 2023. The lease terminates in October 2030, with a Company option to extend for an additional five years. The Company classified the lease as an operating lease and determined that the value of the right of use asset and lease liability at the adoption date was $803, respectively, using a discount rate of 7.00%.

During the three months ended March 31, 2024 and 2023, the Company made combined aggregate payments of $148 and $114, respectively, towards the lease liabilities. As of March 31, 2024 and December 31, 2023, the combined lease liability amounted to $2,371 and $2,519, respectively.

ASC 842 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. During the three months ended March 31, 2024 and 2023, the Company reflected combined amortization of the right of use assets of $164 and $118, respectively, related to the leases, resulting in a combined net asset balance of $2,264 and $2,428 as of March 31, 2024 and December 31, 2023, respectively.

Other Leases

In November 2019, the Company entered into a short-term lease agreement for one of its office facilities, which was subsequently extended until December 2022 and is currently on a month-to-month basis. Rent expense was $9 during the three months ended March 31, 2024 and 2023, respectively.

NOTE 8 - SHAREHOLDERS' EQUITY

Common Stock

Authorized shares

The Company's Certificate of Incorporation authorizes the Company to issue up to 200,000,000 of its common shares. Holders of shares of common stock have full voting rights, one vote for each share held of record. Shareholders are entitled to receive dividends as may be declared by the Company's board of directors (the "Board") out of funds legally available therefore and share pro rata in any distributions to shareholders upon liquidation. Shareholders have no conversion, pre-emptive or subscription rights. All outstanding shares of common stock are fully paid and non-assessable. As of March 31, 2024 and December 31, 2023, there were 26,996,740 and 26,788,986 shares of common stock issued and outstanding, respectively.

Common Stock Issued for Cash Upon Closing of the Company's Private Placements

In May and June 2023, the Company entered into securities purchase agreements (the "Purchase Agreements") with certain investors pursuant to which the Company agreed to sell and issue shares of its common stock in two private placement transactions. The Company agreed to extend certain commitments under the Purchase Agreement totaling $24,000 past their initial due dates.

In November 2023, the Company agreed to extend the funding deadline for $2,000 of the remaining aggregate investment amounts to March 31, 2024. The investor who was obligated to fund $22,000 of the remaining committed investment amounts has not made such payments and has indicated that he does not intend to comply with his investment commitments under the Purchase Agreements. The Company is currently evaluating its potential remedies with respect to this investor's non-compliance with his contractual obligations to the Company.

Grant of Restricted Stock Units (RSU)

The following table summarizes restricted common stock activity during the three months ended March 31, 2024:

	Number of Restricted Shares	Fair Value	Weighted Average Grant Date Fair Value
Non-vested, December 31, 2023	57,900	$ 1,103	$ 22.40
Granted	130,690	852	6.52
Vested	(131,267)	(989)	7.53
Forfeited	—	—	—
Non-vested, March 31, 2024	57,323	$ 966	$ 16.85

During the three months ended March 31, 2024, the Board approved the issuance of a combined total of 130,690 restricted shares of the Company's common stock to certain of its employees. The fair value of the shares on the date of grant was $852 and was recorded during the three months ended March 31, 2024. The restricted common stock was granted under the Company's 2022 Equity Incentive Plan ("the 2022 Plan"). All of these shares, plus an additional 577 restricted shares, vested during the three months ended March 31, 2024.

During the three months ended March 31, 2024, the Company recorded $989 of stock compensation for the fair value vesting of restricted common stock. As of March 31, 2024, $966 of unamortized compensation remained.

Stock Options

In August 2009, the Board approved the adoption of the 2009 Equity Incentive Plan ("the 2009 Plan"). The 2009 Plan was initiated to encourage and enable employees, directors and consultants of the Company to acquire and retain a proprietary interest in the Company by ownership of its common stock. A total of 6,166,666 of the authorized shares of the Company's common stock may be subject to, or issued pursuant to, the terms of the plan. As of March 31, 2024, no shares were available for grant under the 2009 plan.

In September 2018, the Board approved the adoption of the 2019 Equity Incentive Plan ("the 2019 Plan"). The 2019 Plan was initiated to encourage and enable employees, directors and consultants of the Company to acquire and retain a proprietary interest in the Company by ownership of its common stock. The 2019 Plan allows for the following types of awards: (i) incentive stock options ("ISOs"); (ii) nonstatutory stock options ("NSOs"); (iii) stock appreciation rights; (iv) restricted stock awards; (v) restricted stock unit awards ("RSUs"); (vi) other stock awards. The maximum number of shares of our common stock that may be issued under our 2019 Plan is 2,059,073 shares. Outstanding stock awards granted under the 2009 Plan that (i) expire or terminate for any reason prior to exercise or settlement; (ii) are forfeited because of failure to meet a contingency or condition required to vest such shares or otherwise return to us; or (iii) are required or withheld (or not issued) to satisfy a tax withholding obligation in connection with an award or to satisfy the purchase price or exercise price of a stock award can be added to the authorized shares as returning shares, not to exceed 3,774,260 shares. The maximum number of shares of our common stock under our 2019 Plan that may be issued is 5,833,333 shares. As of March 31, 2024, a total of 1,632,314 shares were available for grant under the 2019 plan.

In June 2022, the Board approved the adoption of the 2022 Plan. The 2022 Plan provides for the grant of ISOs to employees, including employees of any parent or subsidiary, and for the grant of NSOs, stock appreciation rights, restricted stock awards, RSUs, performance awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of our affiliates. The 2022 Plan is a successor to the 2019 Plan. No further grants will be made under the 2019 Plan. The maximum number of shares of the Company's common stock under the 2022 Plan that may be issued is 2,800,000 shares. In addition, the number of shares of the Company's common stock reserved for issuance under the 2022 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2024 and continuing through and including January 1, 2032, in an amount equal to 5% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Board. During the three months ended March 31, 2024, no option shares were granted under the 2022 Plan. As of December 31, 2023, a total of 1,922,212 shares were available for grant under the 2022 plan. In January 2024, the number of shares available to be issued under the 2022 Plan automatically increased by 1,339,449 shares, as determined by the Plan, and 3,261,661 shares were available for grant under the 2022 Plan as of March 31, 2024.

In September 2023, the Board approved the adoption of the Company's 2023 Inducement Plan (the "Inducement Plan") to reserve 1,000,000 shares of the Company's common stock to be used exclusively for grants of awards to individuals that were not previously employees or directors of the Company as an inducement material to the individual's entry into employment with the Company. The Inducement Plan provides for the grant of NSOs, stock appreciation rights, restricted stock awards, RSUs, performance-based cash and stock awards, and other stock-based awards. In addition, forms of (i) Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise and (ii) Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement, for both (a) executive officers and (b) employees at or below the vice president level, were adopted and approved for use with the Inducement Plan. The terms and conditions of the Inducement Plan are substantially similar to the Company's stockholder-approved 2022 Plan. During the three months ended March 31, 2024, no awards were granted under the Inducement Plan. As of March 31, 2024, a total of 555,700 shares were available for grant under the Inducement plan.

Option exercise prices are set forth in the grant notice, without commission or other charge, provided however, that the price per share of the shares subject to the option shall not be less than the greater of (i) 100% of the fair market value of a share of stock on the grant date, or (ii) 110% of the fair market value of a share of stock on the grant date in the case of a Participant then owning more than 10% of the total combined voting power of all classes of stock of the Company or any "subsidiary corporation" of the Company or any "parent corporation" of the Company. Options to employees, directors and consultants generally vest and become exercisable over a period not exceeding four years. Options typically expire ten years after date of grant.

The Company's policy is to recognize compensation cost for awards with only service conditions on a straight- line basis over the requisite service period for the entire award. Additionally, the Company's policy is to issue new shares of common stock to satisfy stock option exercises. The Company applied fair value accounting for all share-based payments awards. The fair value of each option granted is estimated on the date of grant using the Black-Scholes option-pricing model.

The table below summarizes the Company's stock option activities for the three months ended March 31, 2024:

	Number of Option Shares	Exercise Price Range Per Share	Weighted Average Exercise Price
Balance, December 31, 2023	5,118,920	$ 6.00 - 24.75	$ 9.76
Granted	—	—	—
Cancelled	—	—	—
Exercised	—	—	—
Expired	—	—	—
Balance, March 31, 2024	5,118,920	$ 6.00 - 24.75	$ 9.76
Vested and exercisable, March 31, 2024	3,855,160	$ 6.00 - 10.50	$ 6.09
Unvested, March 31, 2024	1,263,760	$ 6.00 – 24.75	$ 20.91

The following table summarizes information concerning outstanding and exercisable options as of March 31, 2024:

	Options Outstanding			Options Exercisable		
Range of Exercise Prices	Number Outstanding	Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$ 6.00	3,878,133	4.30	$ 6.00	3,763,653	4.20	$ 6.00
6.01 – 10.50	90,099	1.78	9.52	90,099	1.78	9.52
10.51 – 24.75	1,150,688	9.45	22.26	1,408	9.44	22.40
$ 6.00 - 24.75	5,118,920	5.43	$ 9.76	3,855,160	4.14	$ 6.09

During the three months ended March 31, 2024, the Company extended the option term for two option holders for an additional year through December 31, 2024. The total number of shares that were extended was 51,581 shares. The cost of the stock option modifications was $303 and was recorded during the three months ended March 31, 2024. In September 2022, the Board approved a stock option repricing whereby the exercise price of previously granted and unexercised options held by certain employees, directors and key advisers with exercise prices between $9.00 and $10.50 per share, would be adjusted to $6.00 per share, the closing price of the Company's initial public offering. The total cost of the repricing was $2,733, of which $2,689 was recorded as of December 31, 2023, and $11 was recorded during the three months ended March 31, 2024. The remainder of the cost will be recorded over the future vesting periods of the options.

During the three months ended March 31, 2024, the Company recorded $1,489 of stock compensation for the value of all options vesting during the period. As of March 31, 2024, unvested compensation of $18,090 remained that will be amortized over the remaining vesting period, through September 2027. The aggregate intrinsic value for option shares outstanding at March 31, 2024 was $1,645.

At the time of the issuances of stock options, the Company believed the Company's estimates of the fair value for financial reporting purposes of the Company's common stock were reasonable and consistent with the Company's understanding of how similarly situated companies in the industry were valued.

Stock Warrants

The table below summarizes the Company's warrants activities for the three months ended March 31, 2024:

	Number of Warrant Shares	Exercise Price Range Per Share	Weighted Average Exercise Price
Balance, December 31, 2023	512,759	$ 3.00 - 10.50	$ 7.14
Granted	—	—	—
Cancelled	—	—	—
Exercised	(76,487)	9.00	9.00
Expired	(38,297)	9.00 - 10.50	9.15
Balance, March 31, 2024	397,975	$ 3.00 - 9.00	$ 6.59
Vested and exercisable, March 31, 2024	397,975	$ 3.00 - 9.00	$ 6.59

The following table summarizes information concerning outstanding and exercisable warrants as of March 31, 2024:

	Warrants Outstanding			Warrants Exercisable		
Range of Exercise Prices	Number Outstanding	Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$ 3.00	133,333	2.92	$ 3.00	133,333	2.92	$ 3.00
3.01 – 9.00	264,642	2.89	8.40	264,642	2.89	8.40
$ 3.00 – 9.00	397,975	2.90	$ 6.59	397,975	2.90	$ 6.59

During the three months ended March 31, 2024, warrant holders exercised 76,487 warrant shares at an exercise price of $9.00 per share for proceeds of $688.

The aggregate intrinsic value for warrant shares outstanding at March 31, 2024 was $457.

NOTE 9 - LEGAL MATTERS

As of December 31, 2023, the Company was the defendant in one pending litigation. On November 6, 2023, the Los Angeles County Superior Court granted the Company's motion for summary judgment and issued an order and final judgment dismissing all claims against the Company with prejudice. Although the plaintiff filed a notice of appeal of the dismissal order with the California Court of Appeal, the plaintiff subsequently filed a request for dismissal of his appeal, which was dismissed by the appellate court on February 23, 2024. Accordingly, the order and final judgment dismissing all claims against the Company with prejudice is now final.

In the future, the Company may be involved in additional actual and/or threatened legal proceedings, claims, investigations and government inquiries arising in the ordinary course of our business, including legal proceedings, claims, investigations and government inquiries involving intellectual property, data privacy and security, other torts, illegal or objectionable content, consumer protection, securities, employment, contractual rights, civil rights infringement, false or misleading advertising, or other legal claims relating to our business.

NOTE 10 - SUBSEQUENT EVENTS

Subsequent to March 31, 2024, the Company repaid $1,024 of past due accrued payroll related amounts owed to an employee (see Note 6).

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited consolidated financial statements and related notes appearing in Part I, Item 1 of this Quarterly Report on Form 10-Q (this "Quarterly Report"), and with our audited financial statements and notes thereto for the year ended December 31, 2023, included in our Annual Report on Form 10-K, as amended, for the fiscal year ended December 31, 2023.

Special Note Regarding Forward-Looking Statements

In addition to historical information, some of the statements contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We have based these forward-looking statements on our current expectations and any projections about future events. The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report, particularly including those risks identified in Part II, Item 1A "Risk Factors" and in our other filings with the Securities Exchange Commission (the "SEC").

We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. Statements made herein are as of the date of the filing of this Quarterly Report with the SEC and should not be relied upon as of any subsequent date. Even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

Genelux is a late clinical-stage biopharmaceutical company focused on developing a pipeline of next-generation oncolytic viral immunotherapies for patients suffering from aggressive and/or difficult-to-treat solid tumor types. Our clinical and preclinical product candidates are intended to selectively kill tumor cells and induce a robust immune response against a patient's tumor neoantigens. Importantly, our oncolytic immunotherapy product candidates are "off-the-shelf" personalized immunotherapies. In other words, while we administer the same virus product to different patients, the cellular immune response generated is expected to be specific to the unique neoantigens in that patient. Our product candidate, Olvi-Vec (olvimulogene nanivacirepvec), is a proprietary, modified strain of the vaccinia virus (VACV), a stable DNA virus with a large engineering capacity.

Employing our proprietary selection technology and discovery and development platform (CHOICE), we have developed an extensive library of isolated and engineered oncolytic VACV immunotherapeutic product candidates. These provide potential utility in multiple tumor types in both the monotherapy and combination therapy settings, via physician-preferred administration techniques, including regional (e.g., intraperitoneal), local and systemic (e.g., intravenous) delivery routes. Informed by our CHOICE platform and supported by extensive clinical and preclinical data, we believe we have the capacity to develop a pipeline of treatment options to address high unmet medical needs for those patients with insignificant or unsatisfactory responses to standard-of-care therapies, including chemotherapies.

Since inception, our operations have focused on organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, establishing our intellectual property portfolio, identifying potential product candidates and undertaking preclinical and clinical studies and manufacturing. We do not have any products approved for sale and have not generated any revenue from product sales.

Since inception, we have incurred significant operating losses. Our net losses were $7.9 million and $10.4 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $229.4 million. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, as we advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory approval for our current and future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel and operate as a public company.

We will not generate revenue from commercially approved product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing, and distribution activities.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as, and when needed, could have a material adverse effect on our business, results of operations and financial condition.

At March 31, 2024, we had cash and cash equivalents, and short-term investments, on hand in the amount of $19.6 million. During the year ended December 31, 2023, we closed our initial public offering (IPO) and two private placements (Private Placements) and received $37.8 million of aggregate net proceeds from these offerings. We also received commitments through the Private Placements for the funding of an additional $24.0 million that were due by November 15, 2023. In November 2023, we agreed to extend the funding deadline for $2.0 million of the remaining committed investment amounts to March 31, 2024. The investor who was obligated to fund $22.0 million of the remaining committed investment amounts has not made such payments and has indicated that he does not intend to comply with his investment commitments through the Private Placements. We are currently evaluating our potential remedies with respect to this investor's non-compliance with his contractual obligations to us. We expect our existing cash and cash equivalents, and short-term investments, will last for at least the next 12 months.

Recent Developments

The Company currently is engaged in regulatory study start-up activities of a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV for patients with recurrent NSCLC in the United States. In accordance with our licensing agreement, the Phase 2 clinical trial will be funded in its entirety by our partner in China, Newsoara. In November 2023, we agreed with Newsoara that Genelux would directly engage a contract research organization on mutually agreeable terms to conduct certain startup activities for the NSCLC trial in the U.S. only, with Newsoara reimbursing Genelux for the costs and expenses of such agreed-upon startup activities. Newsoara is permitted to defer such reimbursement payments until the completion of its next round of financing, which Newsoara expects to occur in 2024.

Components of Results of Operations

Net Sales

During the three months ended March 31, 2023, under our license agreement with Newsoara BioPharma Co. Ltd. ("Newsoara"), we invoiced and collected $0.2 million relating to supplying product for Newsoara to use in its clinical trials. During the three months ended March 31, 2024, we recognized revenue of $0.01 million relating to the Company's license agreement with ELIAS Animal Health, LLC.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research and development activities, including our product candidate discovery efforts and preclinical and clinical studies under our research programs, which include:

- employee-related expenses, including salaries, benefits and stock-based compensation expense for our research and development personnel;
- costs of funding research performed by third parties that conduct research and development and preclinical and clinical activities on our behalf;
- costs of manufacturing drug product and drug supply related to our current or future product candidates;
- costs of conducting preclinical studies and clinical trials of our product candidates;
- consulting and professional fees related to research and development activities, including equity-based compensation to non-employees;
- costs of maintaining our laboratory, including purchasing laboratory supplies and non-capital equipment used in our preclinical studies;
- costs related to compliance with clinical regulatory requirements; and
- facility costs and other allocated expenses, which include expenses for rent and maintenance of facilities, insurance, depreciation and other supplies.

Research and development costs are expensed as incurred. Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us by our vendors and analyzing the progress of our preclinical and clinical studies or other services performed. Significant judgment and estimates are made in determining the accrued expense balances at the end of any reporting period.

The successful development of our product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete development of our current or future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of our product candidates, if they are approved. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, rate of progress, and expenses of our ongoing research activities as well as any preclinical studies and clinical trials and other research and development activities;
- establishing an appropriate safety profile;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

A change in the outcome of any of these variables with respect to the development of our current and future product candidates would significantly change the costs and timing associated with the development of those product candidates.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as we commence clinical trials and continue the development of our current and future product candidates. However, we do not believe that it is possible at this time to accurately project expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

General and Administrative Expenses

General and administrative expenses include salaries and other compensation-related costs, including stock-based compensation, for personnel in executive, finance and accounting, business development, operations and administrative roles. Other significant costs include professional service and consulting fees, including legal fees relating to intellectual property and corporate matters, accounting fees, recruiting costs and costs for consultants who we utilize to supplement our personnel, insurance costs, travel costs, facility and office-related costs not included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future as our business expands to support expected growth in research and development activities, including our future clinical programs. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside service providers, among other expenses. We also anticipate increased expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services related to compliance with the rules and regulations of the SEC, and listing standards applicable to companies listed on a national securities exchange, director and officer insurance premiums, and investor relations costs. In addition, if we obtain regulatory approval for any of our product candidates and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing and distribution activities.

Results of Operations

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

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

	March 31, 2024	March 31, 2023
Revenues	$ 8	$ 170
Operating Expenses:		
Research and development	4,010	2,845
General and administrative	4,113	3,787
Total operating expenses	8,123	6,632
Loss from operations	(8,115)	(6,462)
Other income (expenses):		
Interest income	265	—
Interest expense	—	(143)
Debt discount amortization	—	(649)
Financing costs	—	(3,110)
Total other income (expenses), net	265	(3,902)
Net loss	$ (7,850)	$ (10,364)

Research and Development Expenses

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

Research and Development Expenses:	March 31, 2024	March 31, 2023
Employee compensation and related expenses	$ 865	$ 393
Stock compensation, including the cost of stock options and restricted stock grants	1,053	736
Manufacturing and laboratory materials and other expenses	257	93
Outsourced manufacturing services	389	280
Clinical and regulatory expenses	944	826
Facility-related expenses, including depreciation	419	300
Consulting expenses and contract labor	60	208
Other expenses	23	9
Total research and development expenses	$ 4,010	$ 2,845

Research and development expenses were $4.0 million and $2.8 million for the three months ended March 31, 2024 and 2023, respectively, an increase of $1.2 million. Significant variations between periods are primarily a result of a $0.4 million increase in employee compensation and related expenses in 2024, primarily related to new employee hires after the first quarter of 2023; and a $0.3 million increase in stock-related compensation in 2024, relating to the increased cost of stock options and restricted stock units in 2024.

General and Administrative Expenses

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

General and Administrative Expenses:	March 31, 2024	March 31, 2023
Employee compensation and related expenses	$ 599	$ 459
Stock compensation, including the cost of stock options and restricted stock grants	1,739	2,295
Professional services	1,061	674
Facility-related expenses	126	80
Insurance expenses	236	208
Consulting and contract labor expenses	206	36
Other expenses	146	35
Total general and administrative expenses	$ 4,113	$ 3,787

General and administrative expenses were $4.1 million and $3.8 million for the three months ended March 31, 2024 and 2023, respectively, an increase of $0.3 million. Significant variations between periods are primarily a result of a $0.6 million decrease in stock compensation expense in 2024, due to the decrease in the cost of stock options and restricted stock units in 2024 compared to 2023; and a $0.4 million increase in professional service expenses in 2024, primarily resulting from increased corporate legal costs and other professional services related to being a newly publicly traded company.

Other Expenses, net

Other income (expenses), net, were $0.3 million and $(3.9) million for the three months ended March 31, 2024 and 2023, respectively. During the three months ended March 31, 2024, other income consisted of interest income of $0.3 million from the investment into money market funds and short-term investments, while during the same period in 2023, other expenses consisted of interest expense of $0.1 million, debt discount amortization of $0.6 million and financing costs of $3.1 million.

Liquidity and Capital Resources

Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As reflected in the accompanying financial statements, we experienced recurring losses from operations since inception and incurred a net loss of $6.8 million and used cash in operations of $4.4 million during the three months ended March 31, 2024. These factors raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to raise additional funds and implement our strategies. The financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

At March 31, 2024, we had cash and cash equivalents, and short-term investments, in the amount of $19.6 million. The ability to continue as a going concern is dependent on us attaining and maintaining profitable operations in the future and raising additional capital to meet our obligations and repay our liabilities arising from normal business operations when they come due. Since inception, we have funded our operations primarily through equity and debt financings and licensing income, and we expect to continue to rely on these sources of capital in the future.

No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to us. Even if we are able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, cause substantial dilution to our stockholders, in the case of equity financing, or grant unfavorable terms in future licensing agreements.

Cash Flows

The table below summarizes our cash flow activities for the three months ended March 31, 2024 and 2023 (in thousands):

Net cash provided by (used in):	March 31, 2024	March 31, 2023
Operating activities	$ (4,354)	$ (4,590)
Investing activities	(1,691)	(109)
Financing activities	688	14,640
Net increase (decrease) in cash	$ (5,357)	$ 9,941

Operating Activities

During the three months ended March 31, 2024, we used cash from operating activities of $4.4 million, compared to $4.6 million used during the three months ended March 31, 2023. During the three months ended March 31, 2024, we incurred a net loss of $7.9 million and had non-cash expenses of $2.9 million, compared to a net loss of $10.4 million and non-cash expenses of $7.0 million during the three months ended March 31, 2023. The primary non-cash expense during both periods was stock-related compensation totaling $2.8 million and $3.0 million during the three months ended March 31, 2024 and 2023, respectively; and the fair value of warrants issued in connection with the conversion of convertible notes of $3.1 million during the three months ended March 31, 2023. The net change in operating assets and liabilities during the three months ended March 31, 2024 provided cash of $0.6 million, compared to $1.3 million used during the three months ended March 31, 2023. The primary source of cash during the three months ended March 31, 2024 was the increase in accounts payable and accrued expenses of $1.5 million. The primary use of cash during the three months ended March 31, 2023 was the decrease in accounts payable and accrued expenses of $0.9 million.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2024 was $1.7 million, consisting of the net purchases of short-term investments of $1.7 million, and purchases of property and equipment for construction-in-progress of $0.003 million. Net cash used in investing activities for the three months ended March 31, 2023 was $0.1 million, consisting of the purchase of property and equipment.

Financing Activities

During the three months ended March 31, 2024, we provided cash from operating activities of $0.7 million, compared to $14.6 million provided during the three months ended March 31, 2023. For the three months ended March 31, 2024, cash provided by financing activities consisted of proceeds from the exercise of stock warrants of $0.7 million. For the three months ended March 31, 2023, cash provided by financing activities consisted of proceeds from the issuance of proceeds from notes payable - shareholders totaling $0.9 million and proceeds from the sale of common stock related to our IPO totaling $14.5 million, excluding offering costs paid by us.

Net cash used in financing activities during the three months ended March 31, 2023 related to the repayment of notes payable - shareholders totaling $0.5 million and the payment of deferred offering costs of $0.3 million.

Equity Financings

Common Stock Issued for Cash Upon Closing of the Company's Private Placements

In May and June 2023, we entered into securities purchase agreements (the "Purchase Agreements") with certain investors pursuant to which we agreed to sell and issue shares of our common stock in two private placement transactions. Under the Purchase Agreements, we agreed to extend commitments totaling $24.0 million past their initial due dates.

In November 2023, we agreed to extend the funding deadline for $2.0 million of the remaining aggregate investment amounts to March 31, 2024. The investor who was obligated to fund $22.0 million of the remaining committed investment amounts has not made such payments and has indicated that he does not intend to comply with his investment commitments under the Purchase Agreements. We are currently evaluating our potential remedies with respect to this investor's non-compliance with his contractual obligations to us.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue our research and development, initiate and conduct preclinical studies and clinical trials, and seek marketing approval for our current and any of our future product candidates. In addition, if we obtain marketing approval for any of our current or our future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution, which costs we may seek to offset through entry into collaboration agreements with third parties. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We believe that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date of filing of this Quarterly Report. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on a number of factors, including:

- the costs of conducting preclinical studies and clinical trials;
- the costs of manufacturing;

- the scope, progress, results and costs of discovery, preclinical development, laboratory testing, and clinical trials for product candidates we may develop, if any;
- 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 achievement of milestones or occurrence of other developments that trigger payments under any license or collaboration agreements we might have at such time;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive 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;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and research and development activities;
- the costs of operating as a public company; and
- the impact of geopolitical and macroeconomic events, including future bank failures, increased geopolitical tensions between the U.S. and China, the Russia/Ukraine conflict, the Israel-Hamas war and global pandemics on U.S. and global economic conditions that may affect our ability to access capital on acceptable terms, if at all.

We anticipate needing to obtain further funding to achieve our business objectives beyond such date.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our common stockholders' ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of our common stockholders. Additional debt financing, if available, may involve agreements that include restrictive covenants that limit 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 funds through potential collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us. Our ability to raise additional funds also may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from geopolitical and macroeconomic events such as actual or anticipated changes in interest rates and economic inflation, current and future bank failures, global pandemics, geopolitical tensions between the United States. and China and the impact of the Russia/Ukraine conflict and the conflicts in the Middle East. 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 product candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Significant Judgments and Estimates

This 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 accounting principles generally accepted in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in our financial statements prospectively from the date of the change in estimate.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this Quarterly Report, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

Prepaid Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses as of each balance sheet date. 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 cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our research and development expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

The significant estimates in our prepaid research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced. We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense.

In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period.

Stock-Based Compensation

We measure stock options and other stock-based awards granted to employees and directors based on the fair value of the award on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. We recognize forfeitures as they occur. The reversal of compensation cost previously recognized for an award that is forfeited because of a failure to satisfy a service or performance condition is recognized in the period of the forfeiture. Generally, we issue stock options with only service-based vesting conditions and record the expense for these awards using the straight-line method over the requisite service period.

We classify equity-based compensation expense in our statements of operations in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified. In future periods, we expect equity-based compensation expense to increase, due in part to our existing unrecognized stock-based compensation expense and as we grant additional stock-based awards to continue to attract and retain employees.

Determination of the Fair Value of Equity-Based Awards

We estimate the fair value of stock option awards granted using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and subjective assumptions we make, including expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends. Due to the lack of sufficient company-specific historical and implied volatility data, we base the estimate of expected stock price volatility on the historical volatility of a representative group of publicly traded companies for which historical information is available. The historical volatility is generally calculated based on a period of time commensurate with the expected term assumption. We use the simplified method to calculate the expected term for options granted to employees and directors. We utilize this method as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to non-employees, we utilize the contractual term. The risk- free interest rate is based on a U.S. treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero, as we have never paid dividends and do not have current plans to pay any dividends on our common stock. We determine the fair value of restricted common stock awards based on the fair value of our common stock on the date of grant.

Commitments and Contingencies

From time to time, we may have certain contingent liabilities that arise in the ordinary course of business. We evaluate the likelihood of an unfavorable outcome in legal or regulatory proceedings to which we are a party and record a loss contingency on an undiscounted basis when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These judgments are subjective and based on the status of such legal proceedings, the merits of our defenses, and consultation with legal counsel. Actual outcomes of these legal proceedings may differ materially from our estimates. We estimate accruals for legal expenses when incurred as of each balance sheet date based on the facts and circumstances known to us at that time.

Off-Balance Sheet Arrangements

During the three months ended March 31, 2024 and 2023, we did not have, and we do not currently have, any off-balance sheet arrangements (as defined under SEC rules).

Recent Accounting Pronouncements

For a description of recently issued accounting standards that may have a material impact on our financial statements or will otherwise apply to our operations, please see Note 2 to our audited financial statements appearing elsewhere in this Quarterly Report.

Emerging Growth Company Status

As an "emerging growth company," the Jumpstart Our Business Startups Act of 2012 permits us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Item 3. Quantitative and Qualitative Disclosures about Market Risks.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of March 31, 2024. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of March 31, 2024.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our Principal Executive Officer and Principal Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States.

Under the supervision and with the participation of our Principal Executive Officer and Principal Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control-Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this assessment, our management concluded that our internal control over financial reporting was effective at a reasonable assurance level as of March 31, 2024.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act) that occurred during the first quarter of 2024 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

As of December 31, 2023, the Company was the defendant in one pending litigation. On November 6, 2023, the Los Angeles County Superior Court granted the Company's motion for summary judgment and issued an order and final judgment dismissing all claims against the Company with prejudice. Although the plaintiff filed a notice of appeal of the dismissal order with the California Court of Appeal, the plaintiff subsequently filed a request for dismissal of his appeal, which was dismissed by the appellate court on February 23, 2024. Accordingly, the order and final judgment dismissing all claims against the Company with prejudice is now final.

In the future, the Company may be involved in additional actual and/or threatened legal proceedings, claims, investigations and government inquiries arising in the ordinary course of our business, including legal proceedings, claims, investigations and government inquiries involving intellectual property, data privacy and security, other torts, illegal or objectionable content, consumer protection, securities, employment, contractual rights, civil rights infringement, false or misleading advertising, or other legal claims relating to our business.

Item 1A. Risk Factors

Risk Factor Summary

We face many risks and uncertainties, as more fully described in this section under the heading "Risk Factors." Some of these risks and uncertainties are summarized below. The summary below does not contain all of the information that may be important to you, and you should read this summary together with the more detailed discussion of these risks and uncertainties contained in "Risk Factors." Some of the material risks associated with our business include the following:

- We have incurred significant losses since our inception and anticipate that we will incur significant and increasing losses for the foreseeable future and we may never achieve or maintain profitability.
- We will require substantial additional financing to advance the development of our product candidates, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital could force us to delay, limit, reduce or terminate our product development programs, potential commercialization efforts or other operations.
- Our product candidates are in preclinical and clinical stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable.
- 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.
- We currently have only one product candidate, Olvi-Vec, in clinical development. A failure of this product candidate in clinical development would adversely affect our business and may require us to discontinue development of other product candidates based on the same therapeutic approach.
- Preclinical and clinical development involve a lengthy and expensive process with an uncertain outcome and stringent regulations, and delays can occur for a variety of reasons.
- Changes in product candidate manufacturing or formulation may result in additional costs or delay.
- If we are unable to manufacture and release any 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, any product candidates and may lose potential revenues.
- If we fail to comply with federal and state healthcare laws, including fraud and abuse 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 stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.
- If we are unable to obtain, maintain and protect our intellectual property rights for our technology and product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.
- We are highly dependent on our key personnel, including our President, Chief Executive Officer and Chairman. If we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- Unfavorable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations, stock price and prospects.
- Public health crises such as pandemics could materially and adversely affect our preclinical studies and clinical trials, business, financial condition and results of operations.
- The market price of our common stock has been extremely volatile and may continue to be volatile due to numerous circumstances beyond our control, which could result in substantial losses for our stockholders.

Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q (this "Quarterly Report"), including our financial statements and the related notes and "Management's Discussion and Analysis of Results of Operations and Financial Condition," before deciding whether to purchase, hold or sell shares of our common stock. If any of the following risks are realized, our business, financial condition, results of operations, stock price and prospects could be materially and adversely affected. In that event, the price of our common stock could decline, and you could lose part or all of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. The risk factors set forth below that are marked with an asterisk (*) contain changes to the similarly titled risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2023.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will incur significant and increasing losses for the foreseeable future and we may never achieve or maintain profitability.*

We are a clinical stage biopharmaceutical company, and our operations to date have been focused substantially on organizing and staffing our company, business planning, raising capital, creating, assessing, and developing our technology, establishing our intellectual property portfolio, identifying potential product candidates, undertaking preclinical studies, commencing clinical trials and manufacturing. Additionally, as an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful commercialization. We have never generated any revenue from commercially approved product sales and have incurred significant operating losses. Our net losses were $7.9 million and $10.4 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $229.4 million. We expect to continue to incur significant and increasing operating losses 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 expect that it will be several years, if ever, before we have a commercialized product. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- advance the Phase 3 registration clinical trial for our lead product candidate, Olvi-Vec, in platinum resistant/refractory ovarian cancer ("PRROC");
- initiate planned and future clinical trials of Olvi-Vec in other cancer indications;

- discover and develop new product candidates, and conduct research and development activities, preclinical studies and clinical trials;
- manufacture preclinical, clinical and commercial supplies of our product candidates;
- broaden and strengthen our internal manufacturing capabilities, including the expansion and upgrade of our in-house manufacturing facility;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- maintain, expand and protect our intellectual property portfolio;
- hire additional research and development, clinical, scientific and management personnel;
- add operational, financial and management information systems and personnel;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval and we commercialize on our own or in collaboration with others; and
- incur additional legal, accounting and other expenses operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining regulatory approval for product candidates and manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We are only in the development stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts or even continue our operations. A decline in the value of our company could also cause stockholders to lose all or part of their investment.

We will require substantial additional financing to advance the development of Olvi-Vec and any of our future product candidates, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital could force us to delay, limit, reduce or terminate our product development programs, potential commercialization efforts or other operations.*

The development of biopharmaceutical product candidates is capital-intensive. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of, and seek regulatory approval for, our current and future product candidates. If we are able to gain marketing approval of any product candidate that we develop, including Olvi-Vec, we will require significant additional amounts of cash in order to launch and commercialize such product either alone or in collaboration with others. Because the design and outcome of our ongoing, anticipated and any future clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing Olvi-Vec and our other product candidates and programs, and of conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for Olvi-Vec and future product candidates we develop if clinical trials are successful;
- the success of any future collaborations;

- the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;
- the cost and timing of establishing, equipping, and operating our current and planned manufacturing activities;
- the cost of manufacturing Olvi-Vec and future product candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the cost, timing and outcome of seeking U.S. Food and Drug Administration ("FDA") and any other regulatory approvals for any future product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- our ability to establish and maintain healthcare coverage and adequate reimbursement for our future products, if any;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the emergence of competing cancer therapies and other adverse market developments;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company;
- our need and ability to retain key management and hire scientific, technical, medical and business personnel;
- the costs associated with expanding our facilities or building out our laboratory space; and
- the impact of geopolitical and macroeconomic events, including future bank failures, increased geopolitical tensions between the United States and China, the Russia/Ukraine conflict, the conflicts in the Middle East and global pandemics on U.S. and global economic conditions.

Two investors from our private placements (the "Private Placements") were contractually obligated to fund $30.0 million on or before November 15, 2023, of which we have received $6.0 million to date. In November 2023, we agreed to extend the funding deadline for $2.0 million of the remaining aggregate investment amounts to March 31, 2024. The investor who was obligated to fund $22.0 million of the remaining committed investment amounts has not made such payments and has indicated that he does not intend to comply with his investment commitments. We are currently evaluating our potential remedies with respect to this investor's non-compliance with his contractual obligations to us. Besides the Private Placements and the obligations by Newsoara BioPharma Co. Ltd. ("Newsoara") to provide clinical trial funding under our license agreement with Newsoara (the "Newsoara License Agreement"), we do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings and debt financings, or other capital sources such as potential collaborations, strategic alliances, licensing arrangements and other arrangements. Based on our research and development plans, we expect that our existing cash balance will enable us to fund our planned operating expenses and capital expenditure requirements for at least the next 12 months from the date of filing of this Quarterly Report. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. In addition, because the design and outcome of our anticipated and any future clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of Olvi-Vec or any future product candidates. Our existing cash balance may not be sufficient to complete development of Olvi-Vec or any other product candidate. Additionally, although we have commitments from investors to fund the remaining aggregate investment amounts in connection with our Private Placements, we may not receive some or all of the committed proceeds, due to ongoing liquidity constraints or other factors. The failure to receive all or some of the committed proceeds would exhaust our available capital resources sooner than expected and will require us to obtain further funding to achieve our business objectives.

We have never generated any revenue from commercially approved product sales and may never become profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with future partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our development programs. We have no products approved for commercial sale, have not generated any revenue from commercially approved product sales, and do not anticipate generating any revenue from commercially approved product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends heavily on our success in achieving a number of goals, including:

- completing research regarding, and preclinical and clinical development of, product candidates and programs, including Olvi-Vec, and identifying and developing new product candidates;
- obtaining marketing approvals for any product candidates for which we complete clinical trials;
- obtaining regulatory approval to use and sell products generated by our existing or future manufacturing processes for Olvi-Vec and future product candidates, including at our existing manufacturing facility and/or by establishing and maintaining supply and manufacturing relationships with third parties;
- launching and commercializing product candidates for which we obtain marketing approvals, either directly by establishing a sales force and marketing, medical affairs and distribution infrastructure or, alternatively, with a collaborator or distributor;
- establishing and maintaining healthcare coverage and adequate reimbursement for our future products, if any;
- obtaining market acceptance of product candidates that we develop as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if Olvi-Vec or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate that we commercialize on our own or in collaboration with others. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities, to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.

If we are successful in obtaining regulatory approvals to market Olvi-Vec or any future product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indications approved by regulatory authorities are narrower than we expect, the labels for our product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient populations for treatment are narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our stockholders' ownership interest may be diluted. Any future debt financings we undertake, if available, are likely to involve restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. We also could be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves.

Failure to obtain capital when needed on acceptable terms may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations, stock price and prospects. Securing additional financing could also require a substantial amount of time from our management and may divert a disproportionate amount of their attention away from daily activities, which may adversely affect our management's ability to oversee the development of Olvi-Vec or any future product candidates.

The report of our independent registered public accounting firm included a "going concern" explanatory paragraph.

The report of our independent registered public accounting firm on our financial statements as of and for the years ended December 31, 2023 and 2022 included an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern. If we are unable to raise additional capital as and when needed, our business, financial condition and results of operations will be materially and adversely affected, and we may be forced to delay our development efforts, limit our activities and reduce research and development costs. If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The inclusion of a going concern explanatory paragraph by our independent registered public accounting firm, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into licensing and collaboration arrangements or other contractual relationships with third parties and otherwise execute our development strategy.

Risks Related to Product Discovery, Development and Regulatory Approval

Our development of product candidates based on our technology platform is limited, and we do not know whether we will be able to develop any products of commercial value.*

The success of our business depends primarily upon our ability to identify novel product candidates based on our CHOICE platform and to successfully develop and commercialize those product candidates. While we have had promising preclinical study and clinical trial results for Olvi-Vec, to date, it remains our only product candidate that has moved into clinical trials. We have not yet succeeded and may not succeed in demonstrating efficacy and safety in commercializing Olvi-Vec. We also may be unsuccessful in identifying additional product candidates beyond Olvi-Vec using our CHOICE platform, and any of our product candidates may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. In particular, because all of our product candidates have been derived from our CHOICE platform, the failure of any one of our development programs could create a perception that our other programs are less likely to succeed or that our discovery platform is not viable. Similarly, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value and potential of our discovery platform and resulting product candidates.

If any of these events occur, our ability to successfully discover, develop and commercialize any product candidates may be impaired and the value of our company could decline significantly.

Our product candidates are in preclinical and clinical stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable.*

All of our product candidates are in research, preclinical or clinical development. We have not completed the development of any product candidates, we currently generate no revenue, and we may never be able to develop a marketable product. Enrollment of our Phase 2 clinical trial, an open-label, single-arm study, of our lead product candidate, Olvi-Vec, in patients with PRROC, was completed in September 2019, and we reported multiple data readouts in 2020, 2021, 2022 and 2023 for our Phase 2 PRROC clinical trial. We expect the final readout, reported on May 25, 2023 and published in JAMA Oncology in May 2023, to remain essentially unchanged in the final study report. Our Phase 3 registration trial of Olvi-Vec in PRROC initiated enrollment in the third quarter of 2022. We continue to enroll patients in this Phase 3 trial with topline results anticipated in the second half of 2025.

We began regulatory study startup of a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic vaccinia virus ("VACV") for patients with recurrent non-small cell lung cancer ("NSCLC") in the United States in the first half of 2023. Newsoara is generally obligated under the Newsoara License Agreement to fund this trial. In November 2023, we agreed with Newsoara that we would directly engage a contract research organization ("CRO") on mutually agreeable terms to conduct certain startup activities for the NSCLC trial in the United States only, with Newsoara reimbursing us for the costs and expenses of such agreed-upon startup activities. Newsoara is permitted to defer such reimbursement payments until the completion of its next round of financing, which Newsoara expects to occur in 2024. We plan to conduct this Phase 2 trial under our current open investigational new drug application ("IND") and to initiate the trial in the United States in the first half of 2024. Subject to regulatory authorization in China, the Company expects Newsoara eventually to add sites in China and for the parties to conduct this study as a multi-regional clinical trial.

We and Newsoara co-sponsor a Phase 1/2 clinical trial of Olvi-Vec in patients with recurrent SCLC in China, which Newsoara is conducting and initiated the Phase 1 portion in the first half of 2023. We expect to report interim results from the SCLC trial in the second half of 2024. In addition to expecting Newsoara to join our Phase 2 NSCLC trial, as discussed above, we anticipate they will initiate a trial in recurrent ovarian cancer in China.

Additionally, we have a portfolio of oncolytic VACV constructs that are in early-to-mid stages of discovery and preclinical development that may never advance to clinical-stage development or marketing approval. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend on obtaining marketing approvals for, and successfully commercializing our product candidates, either alone or in collaboration with others, and we cannot guarantee that we will ever obtain marketing approval for any of our product candidates. Before obtaining marketing approval for the commercial distribution of our product candidates, we, or a future collaborator, must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy in humans of our product candidates.

The success of our current and future product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of INDs or IND amendments for our planned clinical trials or future clinical trials;
- successful enrollment and completion of clinical trials;
- successful data from our clinical trials that support FDA conclusion of an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt of regulatory and marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;

- obtaining regulatory approval to use our existing or future manufacturing processes for the clinical and commercial manufacture of our product candidates at our existing or future manufacturing facilities or at the facilities of one or more third-party manufacturers with whom we would need to establish supply arrangements;

- successfully launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;

- acceptance of any products we develop and their benefits and uses, if and when approved, by patients, the medical community and third-party payors;

- effectively competing with other therapies;

- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and

- maintaining a continued acceptable safety profile of the products following approval.

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.

We currently have only one product candidate, Olvi-Vec, in clinical development. A failure of this product candidate in clinical development would adversely affect our business and may require us to discontinue development of other product candidates based on the same therapeutic approach.*

We have invested a significant portion of our efforts and financial resources in our oncolytic VACV platform and, in particular, in the development of our lead product candidate, Olvi-Vec. We have completed enrollment for only one Phase 2 clinical trial, an open-label single-arm study, of Olvi-Vec in patients with PRROC in September 2019. Our Phase 3 registration trial of Olvi-Vec in PRROC initiated enrollment in the third quarter of 2022. Our co-sponsored Phase 1/2 clinical trial in SCLC continues to enroll patients in China. We also intend to initiate a Phase 2 clinical trial in patients with NSCLC in the first half of 2024 Olvi-Vec, as well as our other product candidates, are susceptible to the risks of failure inherent at any stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. We will need to successfully complete such trials before submitting a marketing application to the FDA.

We have submitted an IND application with respect to only one product candidate, Olvi-Vec. V2ACT LLC, a joint venture between TVAX Biomedical, Inc. ("TVAX") and us, has also filed its own IND for V2ACT Immunotherapy, a combination of Olvi-Vec and vaccine-enhanced adoptive cell therapy for the treatment of newly diagnosed, surgically-resectable pancreatic cancer patients. For V2ACT Immunotherapy, no clinical trial is yet scheduled to be initiated. We have not previously submitted a biologics license application ("BLA") to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials.

Since Olvi-Vec is based on our oncolytic VACV platform, if Olvi-Vec fails in development as a result of any underlying problem with our oncolytic VACV platform, then we may be required to discontinue development of all product candidates that are based on this therapeutic approach. If we were required to discontinue development of Olvi-Vec or our other future product candidates, or if any of them were to fail to receive regulatory approval or achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability. We can provide no assurance that we would be successful at developing other product candidates based on an alternative therapeutic approach.

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.

We have concentrated all of our research and development efforts on product candidates based on our oncolytic VACV platform, which is novel. We only have conducted clinical development of Olvi-Vec in human cancer patients. Our future success depends on the successful development of our oncolytic VACV platform. Any development problems we experience in the future may cause significant delays or unanticipated costs, and we may not be able to solve any such development problems. Should we encounter development problems, including unfavorable preclinical study or clinical trial results, the FDA or foreign regulatory authorities may place all, or part, of our clinical development on hold or refuse to approve our product candidates, or may require additional information, tests, or trials, which could significantly delay product development and significantly increase our development costs. Moreover, even if we are able to provide the requested information or trials to the FDA, there would be no guarantee that the FDA would accept them or approve our product candidates. We may also experience delays in developing and obtaining regulatory approval for a sustainable, reproducible and scalable manufacturing process, or developing or qualifying and validating product release assays, other testing and manufacturing methods, and our equipment and facilities in a timely manner, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The FDA and comparable foreign regulatory authorities have limited experience with the approval of viral immunotherapies. To date, there is only one FDA-approved viral immunotherapy-talimogene laherparepvec ("IMLYGIC"). Any viral immunotherapies that are approved may be subject to extensive post-approval regulatory requirements, including post-approval studies as well as requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to compliance with these requirements.

Preclinical and clinical development involve a lengthy and expensive process with an uncertain outcome and stringent regulations, and delays can occur for a variety of reasons.*

In order to obtain FDA approval to market a new biological product, we must demonstrate proof of safety as well as purity and potency (i.e., efficacy) in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States. We only have one product candidate currently being evaluated in human clinical development, Olvi-Vec. In addition, the FDA has granted permission to proceed with a clinical trial under the IND for V2ACT Immunotherapy, but no clinical trial has been initiated or is currently scheduled to initiate. The rest of our product candidates are in preclinical development, have not yet been evaluated in IND-enabling studies and their risk of failure is high. We cannot be certain of the timely completion or outcome of our preclinical testing and studies or clinical trials and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies or clinical trials will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all. Additionally, we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin, and we cannot be sure that our planned clinical trials will begin on time or that our ongoing clinical trials will be completed on schedule.

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

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical trials;
- unexpected toxicities observed in preclinical IND-enabling studies precluding the identification of a safe dose to move forward in human clinical trials;
- delays in obtaining regulatory approval for, and production or manufacturing of, clinical supply;
- delays in reaching a consensus with regulatory agencies on study or trial design; and
- regulatory authorities not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

We may experience delays in initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any ongoing or future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize Olvi-Vec or any future product candidates, including:

- delays or failures, which may result in clinical site closures, delays to patient enrollment, patients withdrawing prior to receiving treatment (e.g., catheter implantation failure), patients discontinuing their treatment or follow-up visits or changes to trial protocols;
- regulators or institutional review boards ("IRBs"), may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and/or CROs;
- clinical trials of our product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the unsuccessful implantation of catheters used to deliver Olvi-Vec;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or be lost to follow-up at a higher rate than we anticipate, or may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our product candidates;
- third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- manufacturing delays;
- we, regulators, or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, emergent drug-drug interactions between Olvi-Vec and any of the other therapeutic agents given to the clinical trial subjects or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a biologically, chemically or mechanistically similar therapeutic or therapeutic candidate, or flaws in the design of the trial;
- changes could be adopted in marketing approval policies during the development period, rendering our data insufficient to obtain marketing approval;
- statutes or regulations could be amended, or new ones could be adopted;
- changes could be adopted in the regulatory review process for submitted product applications;
- the cost of clinical trials of our product candidates may be greater than we anticipate, or we may have insufficient funds for a clinical trial or product manufacture or to pay the substantial user fees required by the FDA upon the submission of a BLA or equivalent authorizations from comparable foreign regulatory authorities;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

- the FDA or comparable foreign regulatory authorities may fail to approve the existing or future manufacturing processes or facilities of our company or of third-party manufacturers with which we contract for clinical and commercial supplies;

- we may decide, or regulatory authorities may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical studies, or we may abandon product development programs;

- we may fail to reach an agreement with regulatory authorities or IRBs regarding the scope, design, or implementation of our clinical trials, and the FDA or comparable foreign regulatory authorities may require changes to our study designs that make further study impractical or not financially prudent;

- Regulatory authorities may ultimately disagree with the design or our conduct of our preclinical studies or clinical trials, finding that they do not support product candidate approval;

- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;

- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study or clinical trial, increase the needed enrollment size for the clinical trial or extend its duration;

- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our product candidates;

- the FDA or comparable foreign regulatory authorities may disagree with our trial design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;

- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;

- the FDA or comparable foreign regulatory authorities may disagree with our intended indications;

- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;

- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;

- the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our product candidates; and

- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development, including, for example, due to a longer-and/or-higher-than-expected response rate determination in the active comparator group or a shorter-and/or-lower-than-expected response rate determination in the experimental drug group.

For example, we previously modified our manufacturing process and had to demonstrate analytical comparability to the FDA in order to use Olvi-Vec manufactured by this process in our ongoing Phase 3 PRROC trial. Any future changes to our manufacturing process may similarly require comparability assessments by the FDA and could delay clinical trials or, if the modified manufacturing process is not comparable, result in inconsistencies in trial results that may be difficult to explain.

Our Phase 3 registration trial of Olvi-Vec in PRROC initiated enrollment in the third quarter of 2022. The FDA may issue further comments to our Phase 3 clinical trial protocol and may conclude Olvi-Vec produced in mammalian cells is not comparable to material produced in chick embryo fibroblast ("CEF") cells, and/or place our IND on clinical hold. Placing our IND on clinical hold may cause delays in the initiation of our Phase 3 registration clinical trial. Any delay in obtaining or failure to obtain authorization from the FDA to conduct our Phase 3 clinical trial could materially adversely affect our ability to generate revenue from Olvi-Vec, which may materially harm our business, financial condition, results of operations, stock price and prospects.

As another example, there is currently a national shortage of platinum-based chemotherapies. This shortage initially slowed some site enrollment for our Phase 3 clinical trial investigating the use of Olvi-Vec in PRROC. If the shortage persists, our Phase 2 clinical trial investigating the use of Olvi-Vec in recurrent NSCLC could be negatively impacted. To attempt to mitigate the risk caused by the shortage, we have established our own depot to acquire and store platinum-based chemotherapies. We expect to be able to provide a supply of platinum as needed for our Phase 3 clinical trial for Olvi-Vec in PRROC and our Phase 2 trial for Olvi-Vec in NSCLC, but cannot guarantee that we will be able to resupply adequate amounts on our desired timeline, particularly if shortages continue. The future occurrence of similar shortages of other commercially-available drugs used in our clinical trials could also negatively impact our clinical trials.

Our product development costs will also increase if we experience delays in clinical testing or marketing approvals, and we may not have sufficient funding to complete the testing and approval process for any of our current or future product candidates. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical studies or clinical trials beyond what we currently have planned will be required, will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant delays relating to any preclinical studies or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of our product candidates. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

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 foreign regulatory authorities.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment or retention in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- availability and efficacy of approved therapies for the disease under investigation;
- patient eligibility criteria for the trial in question;
- risks that enrolled subjects will drop out before completion of the trial, including as a result of emergent drug-drug interactions between Olvi-Vec and any of the other therapeutic agents given to the clinical trial subjects or contracting health conditions;

- risks of excessive catheter implantation failures leading to elimination of particular study sites from the trial in question;
- perceived risks and benefits of the product candidate under study;
- the timely initiation of clinical trial sites;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- withdrawal of consent for any reason;
- imbalance in withdrawals between the comparator and treatment arms;
- unforeseen limitations of protocol design; and
- protocol amendment by the sponsor and/or as requested by applicable regulatory authorities.

In addition, our planned clinical trials may 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 trials may instead opt to enroll in a competing clinical trial.

Our inability to enroll a sufficient number of patients for our anticipated and any future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which could have an adverse effect on our business, financial condition, results of operations, and prospects.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.

For our lead product candidate, Olvi-Vec, we completed enrollment, and we reported multiple data readouts in 2020, 2021, 2022 and 2023 for our Phase 2 PRROC clinical trial. We expect the final readout, reported on May 25, 2023 and published in JAMA Oncology in May 2023, to remain essentially unchanged in the final study report. Our Phase 3 registration trial of Olvi-Vec in PRROC initiated enrollment in the third quarter of 2022. Upon completion of this Phase 3 trial, and provided the data demonstrate patient benefit in the PRROC patient population with an acceptable safety profile, we plan to ask for a pre-BLA meeting with the FDA and seek guidance on submission of a marketing application based on the accelerated approval regulations. We anticipate a post-marketing study will be required to confirm a survival benefit. Clinical development is expensive and can take many years to complete and its outcome is inherently uncertain. Olvi-Vec may not perform as we expect in clinical trials, particularly in our open-label, randomized, and controlled Phase 3 registration clinical trial, in which Olvi-Vec may ultimately have a different or no impact on tumors, may have a different mechanism of action than we expect and may not ultimately prove to be safe and effective. The FDA's analysis and interpretation of the data may also differ from ours.

The results of previous clinical trials of Olvi-Vec and results of preclinical studies or early clinical trials of any other product candidate we develop, may not be predictive of the results of subsequent and later-stage clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in registration-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We do not have experience in successfully completing a registration-stage clinical trial and may be unable to execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different 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, variations in conducting clinical trials at different sites, changes in medical practice, FDA requirements based on agency guidelines or precedence which may be more strict for a Phase 3 clinical trial, the rate of dropout among clinical trial participants and changes in the manufacturing process. Moreover, should there be an issue with the design of any of our clinical trials, our results may be impacted. We may not discover such a flaw until the clinical trial is at an advanced stage.

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

From time to time, we may publicly disclose interim, topline, or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, topline, and preliminary 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, such data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim, topline, and preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, interim or topline data and final 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 the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate, or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize Olvi-Vec and any future product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

Fast track designation by the FDA for Olvi-Vec may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that Olvi-Vec or any future product candidate which may receive fast track designation will receive marketing approval.

The FDA has granted a fast track designation for Olvi-Vec for the treatment of patients with PRROC, and we may seek fast track designations for other indications or future product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new product candidates that meet certain criteria. Specifically, biologics are eligible for fast track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. A BLA submitted for a fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the Sponsor pays any required user fees upon submission of the first section of the BLA.

The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Although we have received fast track designation for Olvi-Vec for the treatment of patients with PRROC, and even if we receive additional fast track designations for other indications or any future product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that Olvi-Vec or any future product candidate that may be granted fast track designation will receive marketing approval in the United States. Many product candidates that have received fast track designation have ultimately failed to obtain approval.

We may attempt to secure approval from the FDA through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary regulatory approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

We may in the future seek an accelerated approval for Olvi-Vec or our future product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that such product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor’s agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug’s clinical benefit. If such confirmatory studies fail to confirm the drug’s clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, in December 2022, the Food and Drug Omnibus Reform Act of 2022 was enacted, which, among other things, provided the FDA new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval, and additional oversight over confirmatory trials. Under these provisions, the FDA may, among other things, require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

Prior to seeking approval for Olvi-Vec or any future product candidate we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or obtain any other form of expedited development, review, or approval. Furthermore, if we decide to submit an application for accelerated approval for Olvi-Vec or any future product candidate, there can be no assurance that such submission or application will be accepted or that any expedited development, review, or approval will be granted on a timely basis, or at all. The FDA could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review, or approval for Olvi-Vec or any future product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate, and could harm our competitive position in the marketplace.

Serious adverse events, undesirable side effects (including emergent drug-drug interactions between Olvi-Vec and any of the other therapeutic agents given to the clinical trial subjects) or other unexpected properties of our current or future product candidates may be identified during development or after approval, which could halt their development or lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.

To date, Olvi-Vec is the only product candidate we have tested in humans. The most advanced trial with enrollment completed was our open-label, single-arm Phase 1b/2 clinical trial in PRROC. Enrollment was completed in September 2019, and we reported multiple data readouts in 2020, 2021, 2022 and 2023 for our Phase 2 PRROC clinical trial. We expect the final readout, reported on May 25, 2023 and published in JAMA Oncology in May 2023, to remain essentially unchanged in the final study report. Additionally, we previously conducted five Phase 1 clinical trials and one Expanded Access Program in different indications, using different routes of administration and different dosing regimens. The most common treatment-related toxicities generally observed in our trials from different routes of administration were pyrexia, nausea, chills and fatigue with additional common treatment-related toxicities observed in our intraperitoneal administration trials being abdominal pain and abdominal distension. As we continue our development of Olvi-Vec and initiate clinical trials of any future product candidates, serious adverse events, undesirable side effects or unexpected characteristics may emerge or be reported, causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Even if our product candidates initially show promise in early clinical trials, the side effects of therapies are frequently only detectable after the drug is tested in large, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development and are determined to be attributed to our product candidates, or the result of drug-drug interactions between our product candidate and any of the concomitant therapies given to the trial subjects, we, the FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, could interrupt, delay, or halt clinical trials and could result in a more restrictive label, a Risk Evaluation and Mitigation Strategy ("REMS") or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities 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. Any requests from the FDA or comparable foreign regulatory authority for additional data or information could also result in substantial delays in the approval of our product candidates.

Drug-related side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;

- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties;
- we could be sued and held liable for harm caused to patients; and
- the product may become less competitive, and our reputation may suffer.

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 events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, results of operations, stock price and prospects.

We anticipate that many of our product candidates will be used in combination with third-party drugs and/or devices, some of which may still be in development, and we have limited or no control over the supply, regulatory status or regulatory approval of such drugs and/or devices.

We anticipate developing our product candidates for use in combination with other oncology therapeutics, including chemotherapies and cellular and targeted therapies (e.g., immune checkpoint inhibitors), or medical devices (e.g. intraperitoneal catheter). For example, in our Phase 3 registration clinical trial, we are developing the intraperitoneal (catheter) delivery of Olvi-Vec in combination with a platinum-based chemotherapy doublet and bevacizumab (e.g., AVASTIN). Our ability to develop and ultimately commercialize our product candidates used in combination with platinum-based and other chemotherapies, and bevacizumab, or any other combination products (e.g., cellular and targeted therapies), and used with devices (e.g., catheters) will depend on our ability to access such drugs and devices on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs or devices on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing platinum-based and other chemotherapies, and bevacizumab, or any other combination products, or any devices in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially-viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For our product candidates that may be used in combination with platinum-based and other chemotherapies, and bevacizumab, or any other combination products or any devices, the FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that there are adverse events tied to the interaction of Olvi-Vec with any of the other therapies, or that any positive previous trial results are attributable to the combination therapy and not our product candidates. Moreover, following product approval, the FDA may require that products or devices used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product or device, this may require us to work with a third party to satisfy such a requirement. The ability to obtain cooperation from the third party may impact our ability to respond to the FDA's requests which could impact our ability to achieve regulatory approval. Moreover, developments related to the other product or device may impact our clinical trials as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the safety or efficacy profile of the other product or device, changes to the availability of the approved product or device, and changes to the standard of care.

In the event that any future collaborator or supplier of platinum-based and other chemotherapies, and bevacizumab, or any other products administered in combination, or any devices used, with our product candidates does not supply their products on commercially reasonable terms or in a timely fashion, we would need to identify alternatives for accessing these products. This could cause our clinical trials to be delayed and limit the commercial opportunities for our product candidates, in which case our business, financial condition, results of operations, stock price and prospects may be materially harmed.

We may not be successful in our efforts to expand our pipeline of product candidates and develop marketable products.

We expect initially to develop our lead product candidate, Olvi-Vec. We anticipate pursuing clinical development of other product candidates, alone or in collaboration with our partners. Research programs to identify new product candidates require substantial technical, financial and human resources. Developing, obtaining marketing approval for, and commercializing additional product candidates will require substantial additional funding and will be subject to the risks of failure inherent in medical product development. We cannot assure you that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market additional product candidates for the treatment of cancer, 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.

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

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our product candidates on the potential treatment of certain indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially-viable products.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial, and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

If we do not achieve our product development goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and as a result our share price may decline.

Drug development is inherently risky and uncertain. We cannot be certain that we will be able to:

- complete IND-enabling preclinical studies or develop manufacturing processes and associated analytical methods that meet current good manufacturing practice ("cGMP") requirements in time to initiate or to complete our anticipated or future clinical trials in the timeframes we announce;
- obtain sufficient clinical supply of our product candidates to support our anticipated or future clinical trials;
- initiate clinical trials within the timeframes we announce;
- enroll and maintain a sufficient number of subjects to complete or timely complete any clinical trials; or
- collect and analyze the data from any completed clinical trials in the timeframes we announce.

The actual timing of our development milestones could vary significantly compared to our estimates, in some cases for reasons beyond our control. If we are unable to achieve our goals within the timeframes we announce, the commercialization of our product candidates may be delayed and, as a result, the stock price of our common stock could fall and you may lose all of your investment.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any of our existing or potential future collaboration partners from obtaining approvals for the commercialization of Olvi-Vec, V2ACT Immunotherapy and any other product candidate we develop.

Any current or future product candidate we may develop, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain 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 our 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 our product candidates occur in any jurisdictions, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Even if our 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;
- contain significant safety warnings, including boxed warnings;
- contain significant contraindications, and precautions which could reduce the size of the patient population;
- not be approved with label statements necessary or desirable for successful commercialization;
- 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; or
- be withdrawn from the market because a serious safety issue becomes known after approval is granted.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, takes many years even if successful, and can vary substantially in and among jurisdictions based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. 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. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data 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. It is possible that our product candidates will never obtain the appropriate regulatory approvals necessary for us to commence product sales, or any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

We plan to conduct our Phase 2 clinical trial for Olvi-Vec in recurrent NSCLC in the United States and potentially in China as part of a multi-regional clinical trial with our collaboration partner, Newsoara. However, the FDA and other comparable foreign regulatory authorities may not accept data from such trial, in which case our development plans will be delayed, which could materially harm our business.*

Following FDA authorization, we began regulatory study startup of a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV for patients with recurrent NSCLC in the United States in the first half of 2023. Newsoara is generally obligated under the Newsoara License Agreement to fund this trial. In November 2023, we agreed with Newsoara that we would directly engage a CRO on mutually agreeable terms to conduct certain startup activities for the NSCLC trial in the United States only, with Newsoara reimbursing us for the costs and expenses of such agreed-upon startup activities. Newsoara is permitted to defer such reimbursement payments until the completion of its next round of financing, which Newsoara expects to occur in 2024.

We plan to conduct this trial under our current open IND and, subject to regulatory authorization, potentially launch a multi-regional clinical trial with Newsoara in the United States and China. Newsoara initiated a Phase 1 clinical trial of Olvi-Vec in patients with recurrent SCLC in China in the first half of 2023, and we anticipate they will initiate further trials in recurrent NSCLC and recurrent ovarian cancer in China.

The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with International Conference on Harmonization ("ICH"), and Good Clinical Practice ("GCP") requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

We believe that clinical data generated in China and the United States will be accepted by the FDA and its comparable foreign regulatory equivalents outside of China, which would enable us to commence Phase 3 and possibly registration clinical trials in the United States without the need for us to conduct additional Phase 2 clinical trials in the United States. However, there can be no assurance the FDA or comparable foreign regulatory authorities will accept data from our planned Phase 2 clinical trial in Olvi-Vec. If the FDA or comparable foreign regulatory authorities do not accept any such data, we would likely be required to conduct additional Phase 2 clinical trials, which would be costly and time consuming, and delay aspects of our development plan, which could harm our business.

Conducting clinical trials outside the United States exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

Approval by the FDA or comparable foreign regulatory authorities to market a product candidate will be 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 any products for unapproved or "off-label" uses, 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, the U.S. Department of Justice, the U.S. Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval to market 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 our 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 we develop, including claims comparing our products to other companies' products, and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

Because 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, physicians may in their independent medical judgment 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 do, however, limit communications by biopharmaceutical companies concerning off-label use. Therefore, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA.

If we are found to have impermissibly promoted any products that we may develop, 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, the promotion of biopharmaceutical products is subject to additional FDA requirements and restrictions on promotional statements. If after one or more of our 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.

Engaging in the impermissible promotion of our products, in the United States, 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 (FCA) lawsuits against manufacturers of drugs and biological products have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, up to $3.0 billion, pertaining to certain sales practices and promoting off-label uses. In addition, FCA lawsuits may expose manufacturers to follow-on claims by private payors 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.

Obtaining and maintaining marketing approval for our product candidates in one jurisdiction would not mean that we will be successful in obtaining marketing approval of that product candidate in other jurisdictions, which could prevent us from marketing our products internationally.

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction would not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. If we obtain approval for any product candidate and ultimately commercialize that product in foreign markets, we would be subject to additional risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

Even if our 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 obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA or 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 cGMP requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and 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 our 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 contract manufacturers, could be subject to periodic announced and unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory 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 of the product being less effective than previously thought or other problems with our 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 black boxed warnings, contraindications, precautions, and restrictions on the approved indication or use;
- 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 candidate is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning, untitled, or cyber 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 candidate;
- 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 or criminal penalties, including imprisonment.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, 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 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.

The FDA's policies or those of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, limit the marketability of our product candidates, or impose additional regulatory obligations on us. Changes in medical practice and standard of care may also impact the marketability of our product candidates.

If we are slow or unable to adapt to changes in existing requirements, standards of care, 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.

Should any of the above actions take place, we could be prevented from or significantly delayed in achieving profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

Risks Related to Manufacturing

We are subject to multiple manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.*

The manufacture of biopharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. The process of manufacturing viral immunotherapies, including our product candidates, is particularly complex, time consuming, highly regulated and costly.

Manufacturers of therapeutics often encounter difficulties in production, particularly in scaling up initial production, with such risks including:

- quality control, including stability of the product candidate and quality assurance testing;

- shortages of qualified personnel or key raw materials or components;

- product loss during the manufacturing process, including loss caused by contamination, equipment failure or improper installation or operation of equipment, or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;

- the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, natural disasters, power failures and numerous other factors; and

- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for product candidate batches that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

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.

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

We previously engaged a third-party contract manufacturing organization ("CMO") that specializes in the manufacture of vaccines to produce clinical-grade Olvi-Vec for all of our prior clinical trials.

We have leased a building in San Diego, California and have established and equipped our own cGMP manufacturing facility in order to secure supplies for pivotal studies and commercial launch. This building is intended to give us control over key aspects of the supply chain for our products and product candidates and has additional space for expansion. We recently leased a second building in the same location which, when upgrades are completed, will provide laboratory capabilities and administrative offices.

We have developed a new process for larger-scale manufacturing using a closed, mammalian-cell-based production system. This process is being implemented in our manufacturing facility and is intended to produce Olvi-Vec and other clinical products for use in our subsequent clinical trials and in our commercial launches. We may also make further changes to our manufacturing facilities and processes at various points during development or commercialization, for a number of reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or for other reasons. The manufacturing changes could require changes in raw materials, components and services that are obtained from third-party suppliers. The inability of suppliers to provide those supplies or services or delays in acquiring the supplies or services would delay the manufacture of clinical or commercial product supplies.

These changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our planned or future clinical trials. In some circumstances, changes in the facility or the manufacturing process, as was done with regard to changing to mammalian-cell manufacture, require notification to, or authorization by the FDA or a comparable foreign regulatory authority, which may be delayed or which we may never receive. Such changes may also require, prior to undertaking more advanced clinical trials, additional non-clinical or clinical testing, to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial. For example, we previously modified our manufacturing process and had to demonstrate analytical comparability to the FDA in order to use Olvi-Vec manufactured by this process in our ongoing Phase 3 PRROC trial. Any future changes to our manufacturing process may similarly require comparability assessments by the FDA and could delay clinical trials or, if the product of the modified manufacturing process is not comparable, result in inconsistencies in trial results that may be difficult to explain.

Even if the FDA agrees the products are comparable, the products may, in fact, perform differently and affect the results of our ongoing, planned or future clinical trials. 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 our product candidates and/or jeopardize our ability to commence product sales and generate revenue.

We may rely on CMOs to conduct large-scale manufacture of Olvi-Vec in the future. The inability to identify and contract with suitable CMOs or their failure to meet their obligations to us could affect our ability to develop or commercialize Olvi-Vec in a timely manner.

If the FDA, state or a comparable foreign regulatory authority does not approve our manufacturing facility for the manufacture of our product candidates or if it withdraws any such approval in the future, or our current facility is unable to meet our volume requirements, we may need to find alternative manufacturing facilities, which may significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any alternative manufacturing facility would require obtaining the necessary equipment and materials and, if a third-party manufacturer, the necessary manufacturing know-how, which may take substantial time and investment. We must also receive FDA approval for the use of any manufacturing facility for commercial supply.

In such instance, we may need to enter into an appropriate third-party relationship. We may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our product candidates or programs. Any product candidates we develop compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations that are both capable of manufacturing and filling our viral product for us and willing to do so.

Reliance on third-party providers for certain manufacturing activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations. Under certain circumstances, these third-party providers may be entitled to terminate their engagements with us. If a third-party provider terminates its engagement with us, or does not successfully carry out its contractual duties, meet expected deadlines or manufacture Olvi-Vec or any other product candidates in accordance with regulatory requirements, or if there are disagreements between us and a third-party provider, we may need to identify and qualify replacement suppliers, which may not be readily available or available on acceptable terms. In this instance, we may not be able to complete, or may be delayed in completing, the preclinical studies required to support future IND submissions, the clinical trials required for approval, and commercial supply of Olvi-Vec or any other product candidate, which would thereby have a negative impact on our business, financial condition, results of operations and prospects.

If we are unable to manufacture and release any 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, any product candidates, and may lose potential revenues.

We intend to self-manufacture our clinical trial and commercial product supplies for the foreseeable future. We currently have only one manufacturing facility for use in our clinical trials. Our clinical product supply may be limited, interrupted, or of unsatisfactory quality or may be unavailable at acceptable prices. Any delays in obtaining adequate supplies of our product candidates that meet the necessary quality standards may delay our development or commercialization.

We may be unable to comply with our specifications, applicable cGMP requirements or other FDA, state or foreign regulatory requirements of our product candidates for clinical trials and, if approved, commercial supply, and will be subject to FDA and comparable foreign regulatory authority inspection. These requirements include the qualification and validation of our manufacturing equipment and processes. We may not be able to develop, retain or acquire the internal expertise and resources necessary for effectively managing our ongoing manufacturing operations and complying with these 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 we cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure or maintain regulatory approval for our manufacturing facility. Any such deviations may also require remedial measures that may be costly and/or time-consuming for us to implement, particularly in areas relating to operations, quality, regulatory, facilities and information technology. Any such remedial measures imposed upon us may include the temporary or permanent suspension of a clinical trial or the temporary or permanent closure of our facility and could materially harm our business.

A failure to comply with the applicable regulatory requirements, including periodic regulatory inspections, may result in regulatory enforcement actions against us or our raw material and component suppliers (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, 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 failure or our raw material and component suppliers' 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 problems or delays we experience in 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 any product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

Risks Related to Reliance on Third Parties

We rely, and expect to continue to rely, on third parties to supply and quality-test the ingredients for our product candidates and components for our manufacturing process, and to package and distribute our products.

While we are responsible for the manufacturing of our product candidates, drug substance and drug product, reliance on raw material and component suppliers entails risks, including:

- reduced control for certain aspects of our manufacturing activities;
- termination or nonrenewal of the applicable supplier and service agreements in a manner or at a time that is costly or damaging to us;
- variability of properly released raw materials between batches from a single supplier or between suppliers;
- the possible breach by our third-party suppliers and service providers of our agreements with them;
- the failure of our third-party suppliers and service providers to comply with applicable regulatory requirements;
- the inability to provide adequate supplies of our product;
- disruptions to the operations of our third-party suppliers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Any failure or refusal to supply our product candidates, raw materials or components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. In addition, we do not have any long-term commitments or guaranteed prices from our suppliers of raw materials, manufacturing equipment components or devices or combination products. In particular, any change in our suppliers could require significant effort and expertise because there may be a limited number of qualified replacements. Further, the terms of any new arrangement could be less favorable and transfer costs relating to technology and processes could be significant.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, impact our ability to successfully commercialize any of our product candidates or otherwise harm our business, financial condition, results of operations, stock price and prospects. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure or total or partial suspension of product manufacture.

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates or any other product candidates that we may develop in the future.

We rely, and will rely, on third-party CROs, study sites and others to conduct, supervise, and monitor our preclinical studies and clinical trials for our product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to support future approval of our product candidates, or we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities would be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical studies are conducted in accordance with the FDA's Good Laboratory Practice regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as GCP guidelines, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions. For example, the data generated in our trials may not have been appropriately collected or documented, and thereby be deemed unreliable and the FDA or comparable foreign regulatory authorities may conclude the study findings are not adequate and require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our trials comply with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on one or more government-sponsored databases, e.g., ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not our employees, and except for remedies available to us under our agreements with such third parties we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates; or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We will also rely on other third parties to store and distribute our product candidates for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of our product candidates, which could result in additional losses and deprive us of potential product revenue.

We have entered into, and may in the future enter into, certain collaboration agreements and strategic alliances to maximize the potential of our product candidates, and we may not realize the anticipated benefits of such collaborations or alliances. We expect to continue to form collaborations in the future with respect to our product candidates, but may be unable to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

We may form or seek other strategic alliances, joint ventures, or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates we develop. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or other anticipated benefits that led us to enter into the arrangement. Additionally, the success of any collaboration arrangements may depend on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

If we are not able to establish future collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans for one or more of our other development programs.

We face significant competition in seeking appropriate additional collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

Our current and any future collaborations are not a guarantee of success, and all collaborations are as risky, or more risky, than undertaking the activities ourselves.*

Our current collaborations with TVAX and Newsoara, and potential future collaborations we might enter into for Olvi-Vec or our other product candidates, may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on 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 clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could fail to make timely regulatory submissions for a product candidate;

- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or us to regulatory enforcement actions;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or 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;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

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

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;

- collaborators may not properly 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; and

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

For example, Newsoara is generally obligated under the Newsoara License Agreement to fund a Phase 2, open-label, randomized, and controlled clinical trial designed to evaluate the efficacy and safety of intravenously delivered Olvi-Vec oncolytic VACV for patients with recurrent NSCLC in the United States, which began regulatory study startup in the first half of 2023. Newsoara has also agreed to reimburse us for the costs and expenses of a CRO to conduct certain startup activities for the NSCLC trial in the United States only, but is permitted to defer such reimbursement payments until the completion of its next round of financing, which Newsoara expects to occur in 2024. If Newsoara is unable or unwilling to provide this funding and/or reimbursement in a timely manner or at all, we would need to obtain the funding on our own and/or scale back or discontinue these clinical development activities.

In addition, all of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report also apply to the activities of any of our current or future collaborators.

Collaborations with biopharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

If any collaborations we have entered into or might enter into do not result in the successful development and commercialization of products or if one of our collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates and our product platform.

Additionally, if any collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, 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 other government agencies 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 drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, the FDA and regulatory authorities outside the United States adopted restrictions or other policy measures in response to the COVID-19 pandemic that diverted resources and delayed their attention to routine submissions. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Commercialization

If we, or our collaboration partners, are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.

If we, or our collaboration partners, are successful in obtaining marketing approval from applicable regulatory authorities for Olvi-Vec or any other product candidate, our ability to generate revenues from any such products will depend on our success in:

- launching commercial sales of such products, whether alone or in collaboration with others;
- receiving approved labels with claims that are necessary or desirable for successful marketing, and that do not contain safety or other limitations that would impede our ability to market such products;
- creating market demand for such products through marketing, sales and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize such products in the United States;
- creating partnerships with, or offering licenses to, third parties to promote and sell such products in foreign markets where we receive marketing approval;
- manufacturing such products in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- maintaining patent and trade secret protection and regulatory exclusivity for such products;
- achieving market acceptance of such products by patients, the medical community, and third-party payors;
- achieving coverage and adequate reimbursement from third-party payors for such products;
- achieving patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement from third-party payors;
- competing effectively with other therapies; and
- maintaining a continued acceptable safety profile of such products following launch.

To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.*

The development and commercialization of cancer immunotherapy products is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. There are a number of large biopharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of solid tumors, including viral immunotherapy and cancer vaccine approaches. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

We are aware of a number of companies developing competing therapies for the treatment of cancer which generally fall into the following treatment groups:

- Oncolytic viral immunotherapies, including Amgen's IMLYGIC (talimogene laherparepvec), the only FDA-approved oncolytic immunotherapy, which is approved for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery and is in development for several other indications and Daiichi Sankyo Company, Limited's DELYTACT (teserpaturev/G47Δ), which received conditional and time-limited marketing approval in Japan as a regenerative medical product for treatment of malignant glioma. Other oncolytic viral immunotherapies in development include those by companies such as AstraZeneca PLC (AstraZeneca), Boehringer Ingelheim, CG Oncology, Inc., Candel Therapeutics, Inc., DNAtrix Inc., Imugene Limited, Johnson & Johnson, Merck & Co., Inc. (Merck), Oncolytics Biotech Inc., Otsuka Holdings Co. Ltd., Pfizer Inc., PsiOxus Therapeutics, Ltd., Regeneron Pharmaceuticals, Inc., Replimune Group, Inc., SillaJen, Inc. (SillaJen), Targovax USA, Theriva Biologics, Inc., Transgene SA (Transgene), Turnstone Biologics Corp. and Vyriad, Inc.;

- Approved immunotherapy antibodies and immunotherapy agents in clinical development, including antibody agents, bispecific T cell engagers, including those in development by Amgen, and immuno-oncology companies focused on IL-12, such as Ziopharm Oncology Inc.;

- Cancer vaccines, including personalized vaccines and those targeting tumor neoantigens, including neoantigen therapies in development by companies such as Advaxis, Inc., Agenus Inc., AstraZeneca, Bavarian Nordic A/S, BioNTech SE, Genocea Biosciences, Inc., Gritstone Oncology, Inc., Heat Biologics, Inc., ImmunityBio, Inc., IMV Inc., Moderna, Inc., SOTIO a.s., Transgene, and VBI Vaccines Inc.;

- Cell-based therapies, including tumor infiltrating lymphocytes in development by Iovance Biotherapeutics, Inc., TVAX and Turnstone Biologics, Corp. and approved and in-development CAR T cell therapies, including those commercialized by BMS, Gilead Sciences Inc. and Novartis AG, T cell receptor and NK cell therapies;

- Therapies aimed at activating innate immunity such as those targeting stimulator of interferon genes protein (and toll-like receptors including those in development by Bristol-Myers Squibb Company, Checkmate Pharmaceuticals Inc., Chinook Therapeutics Inc., GlaxoSmithKline plc, Idera Pharmaceuticals, Inc., Merck, Mologen AG, Nektar Therapeutics, TriSalus Life Sciences, and UroGen Pharma Inc.; and

- Traditional cancer therapies, including chemotherapy, surgery, radiation and targeted therapies.

We are aware of several other companies developing therapies based on VACV. To our knowledge, the only clinical product based on VACV that has advanced beyond Phase 1 clinical development is Pexa-Vec, being jointly developed by SillaJen and Transgene. Pexa-Vec has a different product profile from Olvi-Vec, including a different strain of VACV and different transgenes. In August 2019, SillaJen announced the discontinuation of its Phase 3 PHOCUS trial of Pexa-Vec in advanced liver cancer for futility.

We are also aware of other companies either marketing or focused on developing competing therapies for the treatment of ovarian cancer, including PRROC:

Currently marketed products for ovarian cancer include generic products cisplatin (manufactured by 18 companies), carboplatin (manufactured by 22 companies) and paclitaxel (manufactured by 19 companies), along with the following brand products (and generic manufacturers): Abbvie's ELAHERE, Sanofi-Aventis's TAXOTERE (17 manufacturers), Celgene Corp.'s ABRAXANE (one manufacturer), Esai Inc.'s HEXALEN, Roche Holding AG's (Roche) XELODA, Roche/Genentech, Inc.'s AVASTIN (four manufacturers), Baxter Healthcare's CYTOXAN and LFEX, Etoposide (10 manufacturers), Eli Lilly and Company's GEMZAR (15 manufacturers) and ALIMTA (14 manufacturers), Pfizer Inc.'s CAMPTOSAR (19 manufacturers), Janssen Pharmaceutical's DOXIL (one manufacturer), Aspen Pharmacare's ALKERAN, Meitheal Pharmaceuticals's TOPOTECAN, Laboratoires Pierre Fabre's NAVELBINE (four manufacturers), GSK's Zejula, AstraZeneca's LYNPARZA, and Clovis Oncology's RUBRACA.

Product candidates in registration trials or later development for PRROC include:

- Nemvaleukin alfa, an engineered interleukin-2 by Mural Oncology;
- Relacorilant, an anti-glucocorticoid, by Corcept Therapeutics Inc.; and
- Luveltamab tazevibulin, an anti-folate receptor alpha (FolRα) antibody drug conjugate (ADC), by Sutro Biopharma.

While certain of our product candidates may be used in combination with other drugs with different mechanisms of action, if and when marketed they will still compete with a number of drugs that are currently marketed or in development that also target cancer. To compete effectively with these drugs, our product candidates will need to demonstrate advantages in clinical efficacy and safety compared to these competitors when used alone or in combination with other drugs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies. Our competitors also may obtain FDA or comparable foreign regulatory authorities' approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by third-party payors' coverage and reimbursement decisions.

Many of the companies with which we are competing or may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in developing or acquiring technologies complementary to, or necessary for, our programs. If we are unable to successfully compete with these companies, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If we are unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market and sell our product candidates, if they are approved, the revenues that we generate may be limited and we may never become profitable.

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of any products that we may develop. If and when our product candidates receive marketing approval, we intend to commercialize our product candidates on our own or in collaboration with others and potentially with pharmaceutical or biotechnology partners in other geographies. In order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so. Should we decide to move forward in developing our own marketing capabilities, we may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of the FDA or comparable foreign regulatory authority requirements or other reasons, we would incur these expenses prior to being able to realize any revenue from sales of our product candidates. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our product candidates. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may also or alternatively decide to collaborate with third-party marketing and sales organizations to commercialize any approved product candidates, in which event, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other biopharmaceutical and biotechnology companies, including oncology-focused companies, to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development.

In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize our product candidates, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, stock price and prospects. Factors that may inhibit our efforts to commercialize our product candidates include:

- the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing our product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training personnel, including sales and marketing personnel, on compliance matters and monitoring their actions;
- an inability to secure coverage and adequate reimbursement by third-party payors, including government and private health plans;
- the unwillingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement from third-party payors;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for our personnel, including sales or marketing personnel, who fail to comply with applicable law;
- 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 or engaging a contract sales organization.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community necessary for commercial success. The revenues that we generate from their sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval does not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. Market acceptance of our product candidates by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any product for which we receive marketing approval will depend on a number of factors, including:

- the efficacy of our product, including in combination with other cancer therapies;
- the commercial success of any cancer therapies with which our product may be co-administered;
- the prevalence and severity of adverse events associated with our product or those products with which it is co-administered;
- the clinical indications for which our product is approved and the approved claims that we may make with respect to the product;
- limitations or warnings contained in the FDA-approved labeling of the product or the labeling approved by comparable foreign regulatory authorities, including potential limitations or warnings for our product that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our product, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of our product and any products with which it is co-administered;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of coverage and adequate reimbursement by third-party payors, such as private insurance companies and government healthcare programs, including Medicare and Medicaid;
- the ability to have our product placed on approved formularies;
- patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement from third-party payors;
- the price concessions required by third-party payors to obtain coverage and adequate reimbursement;
- the extent and strength of our marketing and distribution of our product;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our product or to which we agree as part of a REMS or voluntary risk management plan;
- the timing of market introduction of our product, as well as competitive products;
- our ability to offer our product for sale at competitive prices;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our raw material supplier and service provider support;
- the actions of companies that market any products with which our product is co-administered;
- the approval of other new products;
- adverse publicity about our product or any products with which it is co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

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. If the market opportunities for any product candidates we develop are smaller than we believe they are, our potential revenues may be adversely affected, and our business may suffer.

The potential market opportunities for our product candidates are difficult to estimate and will depend in large part on the drugs with which our product candidates are co-administered and the success of competing therapies and therapeutic approaches. In particular, the market opportunity for viral immunotherapies is hard to estimate given that it is an emerging field with only one existing FDA-approved viral immunotherapy, T-VEC, which has yet to enjoy broad market acceptance. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. Our estimates of the potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe, and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with our product. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities. Additionally, because of the potential that any product candidates we develop could cure a target disease, we may not receive recurring revenues from patients and may deplete the patient population prevalence through curative therapy.

Negative developments in the field of immuno-oncology could damage public perception of our oncolytic VACV platform and our product candidates, including Olvi-Vec, and negatively affect our business.

The commercial success of our product candidates will depend in part on public acceptance of the use of cancer viral immunotherapies. Adverse events in clinical trials of our product candidates, including Olvi-Vec, or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments with respect to the field of immuno-oncology that may occur in the future, including in connection with competitor therapies, or with respect to products with which our product is co-administered, could result in a decrease in demand for Olvi-Vec or any other 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 cancer 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. As a result, we may not be able to continue or may be delayed in conducting our development programs.

As our product candidates consist of oncolytic VACVs, adverse developments in anti-cancer vaccines or clinical trials of other viral immunotherapy products based on viruses may result in a disproportionately negative effect for Olvi-Vec or our other product candidates as compared to other products in the field of immuno- oncology that are not based on viruses. We do not fully understand the biological characteristics of our therapeutic viruses, and their interactions with other drugs and the human immune and other defense systems, which may cause us to fail to demonstrate the safety and effectiveness of our product candidates in clinical trials. Therapeutic viruses are novel, and we are still determining the biological characteristics of these viruses. In addition, we are still investigating the response of the human immune system to our therapeutic viruses, and the immune system may play a role in limiting their tumor-killing effect. We also do not know the extent to which therapeutic viruses and our treatment processes may be toxic. Moreover, we do not understand all of the many factors that contribute to the formation of each individual patient's cancer; these factors make each tumor unique. The novelty and scientific uncertainties regarding our therapeutic viruses and the uniqueness of human cancers from patient to patient increase the risk that we will not successfully develop our product candidates or prove their safety and effectiveness in clinical trials. Even if we succeed in developing our product candidates, our product candidates may not have a therapeutic effect in a broad patient population.

Future negative developments in the field of immuno-oncology or 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 Olvi-Vec or our other product candidates.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain and protect our intellectual property rights for our technology and product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.*

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our technology, including our oncolytic VACV platform, and Olvi-Vec, V2ACT Immunotherapy and our other product candidates. We also rely in part on trade secret, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our technology and product candidates.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed patents and any patents we own are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States.

Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive product candidates. The scope of a patent may also be reinterpreted after issuance. The rights that may be granted under our issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. If we are unable to obtain and maintain patent protection for our technology or for Olvi-Vec, V2ACT Immunotherapy or our other product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize products similar or superior to ours in a non-infringing manner, and our ability to successfully commercialize Olvi-Vec, V2ACT Immunotherapy or our other product candidates and future technologies may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

In addition, the patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. It is also possible that we will fail to identify patentable aspects of our research and development efforts in time to obtain patent protection.

For the core technology in our CHOICE platform and Olvi-Vec and our other product candidates, patents have issued and applications are pending at each of the U.S. provisional, Patent Cooperation Treaty, and national stages with, at a minimum, filings submitted to the United States, European Patent Conventions and Japan. As of March 31, 2024, our patent portfolio consisted of 19 issued U.S. patents, one pending U.S. patent application, 14 issued foreign patents, and six pending foreign patent applications, which relate generally to the composition of our current and potential future products, and their methods of use. V2ACT LLC has exclusive rights to V2ACT Immunotherapy under one issued U.S. patent, one pending U.S. patent application and two pending non-U.S. patent applications. Any future provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Although we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any of our future patent applications will result in the issuance of patents that effectively protect our technology or Olvi-Vec, V2ACT Immunotherapy or our other product candidates, or if any of our future issued patents will effectively prevent others from commercializing competitive products. We may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office ("USPTO"). Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, or that we were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the inventions claimed in such applications unless and until a patent issues from such applications with a claim that covers infringing third-party activity. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we license from third parties or own in the future may be challenged in the courts or patent offices in the United States and abroad, including through opposition proceedings, derivation proceedings, post-grant review, *inter partes* review, interference proceedings or litigation. Such proceedings may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection for our technology. Protecting against the unauthorized use of our patented inventions, trademarks and other intellectual property rights is expensive, time consuming, difficult and in some cases may not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. If we are unable to obtain, maintain, and protect our intellectual property, our competitive advantage could be harmed, and it could result in a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

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

We may need to obtain licenses from others to advance our research and development activities or allow the commercialization of our current or future product candidates. We expect any such license agreements will impose various development, diligence, commercialization, and other obligations on us. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by the intellectual property under any such license agreements. If such in-licenses were to be terminated, or if the underlying patents were to fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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 may license intellectual property or technology from third parties 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 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.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to seeking patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of our trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators, contractors, and other third parties who have access to our trade secrets. Our agreements with employees and consultants also provide that any inventions conceived by the individual employee or consultant in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information including a breach of our confidentiality agreements. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time consuming, and the outcome is unpredictable. In addition, some courts in and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. The disclosure of our trade secrets or the independent development of our trade secrets by a competitor or other third party would impair our competitive position and may materially harm our business, financial condition, results of operations, stock price and prospects.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends on our ability and the ability of any future collaborators to develop, manufacture, market and sell Olvi-Vec and our other product candidates, and to use our related proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any other future product candidates, including interference proceedings, post-grant review, *inter partes* review and derivation proceedings before the USPTO. Third parties may assert infringement or other intellectual property claims against us based on existing patents or patents that may be granted in the future. 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 pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that such intellectual property rights are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing and commercializing Olvi-Vec and our other product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing Olvi-Vec or our other product candidates. In addition, in any such proceeding or litigation, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material adverse effect on our business. 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.

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

Furthermore, we plan to develop our product candidates in combination with products developed by companies that may be covered by patents or licenses held by those entities to which we do not have a license or a sublicense. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with Olvi-Vec or our other product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

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

Filing, prosecuting and defending patents on our technology 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 and practices 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 and/or manufacture their own products, and 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 and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the granting or enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to obtain patent rights or stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally in those countries. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial cost 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 protect and enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

In addition, the laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and those foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries. Furthermore, biosimilar product manufacturers or other competitors may challenge the scope, validity and enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or proceedings.

Moreover, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and results of operations may be adversely affected.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and to maintain patents after they are issued. For example, periodic maintenance fees, renewal fees, annuity fees and various other government fees on issued patents and patent applications often must be paid to the USPTO and foreign patent agencies over the lifetime of our licensed patents or any patents we own. In certain circumstances, we may rely on future licensing partners to take the necessary action to comply with these requirements with respect to licensed intellectual property. Although an unintentional lapse can be cured for a period of time by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, 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. If we fail to obtain and maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to Olvi-Vec or our other product candidates, which could have a material adverse effect on our business.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect Olvi-Vec, V2ACT Immunotherapy and our other product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or other jurisdictions in which we have or seek patent protection could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the "Leahy-Smith Act") signed into law in the United States on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe our licensed patents or any patent we own, or misappropriate or otherwise violate our intellectual property rights. Litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets, or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Our licensed patents and any patents we own in the future may become involved in priority or other intellectual property related disputes. 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. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of our owned or licensed intellectual property rights. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to conduct intellectual property related litigations or proceedings than we can. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation and other intellectual property related proceedings could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or 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. An adverse result in any litigation or other intellectual property related proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in the United States, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock, and could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market. Any of the foregoing may have a material adverse effect our business, financial condition, results of operations, stock price and prospects.

We may be subject to claims by third parties asserting that we, our employees or any future collaborators have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management team, were previously employed at, or consulted for, universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these people, including each member of our senior management team, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment or consulting agreements, that assigned ownership of intellectual property relating to work performed under such agreements to the contracting third party. Although we try to ensure that our employees do not use, claim as theirs, or misappropriate the intellectual property, proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used, claimed as theirs, misappropriated or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of third parties or are in breach of non-competition or non-solicitation agreements with our competitors.

We could be subject to claims that we or our employees, including senior management, have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors or others. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may 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. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to Olvi-Vec and our other product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers, competitors or other parties. An inability to incorporate such technologies or features would have a material adverse effect on our business, and may prevent us from successfully commercializing Olvi-Vec and our other product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or consultants. A loss of key personnel or their work product could hamper or prevent our ability to develop and commercialize Olvi-Vec and our other product candidates, which could have an adverse effect on our business, financial condition, results of operations, stock price and prospects.

If we obtain any issued patents covering our technology, such patents could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign regulatory authority.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering any of our technology, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar 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, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect Olvi-Vec, V2ACT Immunotherapy and our other product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. For example, with respect to the validity of our licensed patents or any patents we obtain in the future, we cannot be certain that there is no invalidating prior art of which we, our patent counsel or our licensing partner's patent counsel(s), and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on Olvi-Vec, V2ACT Immunotherapy and our other product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and our product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated.

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 may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, such as Olvi-Vec and our other 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.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, but no longer than 14 years from the product's approval date, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their products earlier than might otherwise be the case, which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

The enactment of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") as part of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA") created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biological products, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period.

Olvi-Vec and our other product candidates are all biological product candidates. We anticipate being awarded market exclusivity for each of our biological product candidates that is subject to its own BLA for 12 years in the United States, 10 years in Europe and significant durations in other markets. However, the term of the patents that cover such product candidates may not extend beyond the applicable market exclusivity awarded by a particular country. For example, in the United States, if all of the patents that cover our particular biological product expire before the 12-year market exclusivity expires, a third party could submit a marketing application for a biosimilar product four years after approval of our biological product, the FDA could immediately review the application and approve the biosimilar product for marketing 12 years after approval of our biological product, and the biosimilar sponsor could then immediately begin marketing. Alternatively, a third party could submit a full BLA for a similar or identical product any time after approval of our biological product, and the FDA could immediately review and approve the similar or identical product for marketing and the third party could begin marketing the similar or identical product upon expiry of all of the patents that cover our particular biological product.

There is also a risk that this exclusivity could be changed in the future. For example, this exclusivity could be shortened due to congressional action or through other actions, including future proposed budgets, international trade agreements and other arrangements or proposals. Additionally, there is a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. The extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. It is also possible that payors will give reimbursement preference to biosimilars over reference biological products, even absent a determination of interchangeability.

To the extent that we do not receive any anticipated periods of regulatory exclusivity for our product candidates, or the FDA or foreign regulatory authorities approve any biosimilar, interchangeable, or other competing products to our product candidates, it could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

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 current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive 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.

During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. 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. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to Government Regulation

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

Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable healthcare fraud and abuse, and other healthcare laws, which may constrain the business or financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs.

- The federal civil and criminal false claims laws, including, without limitation, the civil FCA, and the federal Civil Monetary Penalties Law, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government.

- The Health Insurance Portability and Accountability Act ("HIPAA"), which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.

- The U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biological products and medical devices.

- The federal physician payment transparency requirements, sometimes referred to as the Physician Payments Sunshine Act, created under the ACA and its implementing regulations, which require certain manufacturers of drugs, devices, biological products and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members.

- Analogous state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or that apply regardless of payor; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; and state and local laws requiring the registration of pharmaceutical sales representatives.

If we or our operations 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 significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, imprisonment, 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, additional reporting requirements and/or oversight if we become subject to corporate integrity agreements or similar agreement to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, 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 may be subject to significant criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in U.S. federal or state 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 such 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.

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.

In both domestic and foreign markets, sales of our products will depend in part upon the availability of coverage and adequate reimbursement from third-party payors or placement on approved product formularies. 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. Third-party payors establish reimbursement levels. Therefore, 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. 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. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost. Our failure to obtain or maintain timely or adequate pricing or formulary placement of our products, or failure to obtain such formulary placement at favorable pricing may negatively impact our revenue. Additionally, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 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 third-party payors.

A significant trend within the healthcare industry is cost containment, both in the United States and elsewhere. Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs, including use of formularies. Exclusion of a product from a formulary or other restrictions can significantly impact drug usage in the patient population and beyond. Consequently, pharmaceutical companies compete to gain access to formularies for their products, typically on the basis of unique product features, such as greater efficacy, better patient ease of use, or fewer side effects, as well as the overall cost of the therapy. Certain 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. 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. 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, 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.

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.

An inability to promptly obtain coverage and adequate reimbursement from third-party 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 third-party 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. For example, the ACA was passed in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers and continues to significantly impact the U.S. pharmaceutical industry.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 (the "Tax Act"), includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period 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. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional Congressional action is taken.

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 of 2013 imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Further, manufacturers have product investigation, quarantine, disposition, and 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.

There has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biological products. Such scrutiny has resulted in presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

At the federal level, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA directs the Secretary of HHS to establish a Drug Price Negotiation Program (the Program) to lower prices for certain single-source prescription drugs and biologics covered under Medicare Parts B and D, based on criteria established under the IRA. Under the Program, the Secretary of HHS will publish a list of "selected drugs," and will then negotiate maximum fair prices ("MFP") with their manufacturers. Beginning in 2026, the first year of the Program, the number will be limited to 10 Part D drugs and biologics. By 2029, and in subsequent years thereafter, the number will increase to 20 drugs and biologics covered under Part D and Part B. Agreements between HHS and manufacturers will remain in place until a drug or biologic is no longer considered a "selected drug" for negotiation purposes. Manufacturers who do not comply with the negotiated prices set under the Program will be subject to an excise tax based on a percentage of total sales of a "selected drug" up to 95% and the potential of civil monetary penalties. Further, the IRA imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first 10 drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry and could negatively affect our business and financial condition. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Additionally, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that practice will continue under the new framework.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA.

Any new laws or regulations, including those that may result in additional reductions in Medicare and other healthcare funding, could have a material adverse effect on customers for our products, if approved, and, accordingly, on our results of operations.

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.

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, and other consequences, 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 U.S. Foreign Corrupt Practices Act ("FCPA") and other anti-corruption laws that apply in countries where we do business. The FCPA and these other anti- corruption laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. We can be held liable for the corrupt or other illegal activities of our personnel or intermediaries, even if we do not explicitly authorize or have prior knowledge of such activities.

We are also subject to other laws and regulations governing our international operations, 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. 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. An investigation of any potential violations of anti-corruption laws or trade control laws by U.S. or other authorities could also have an adverse impact on our reputation, our business, financial condition, results of operations, stock price and prospects.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of our business, we collect, receive, process, generate, use, transfer, make accessible, protect, secure, dispose of, transmit and store (collectively, "process") personal data and other sensitive information, including proprietary and confidential business data, intellectual property, trade secrets, clinical trial data and sensitive third-party data. Accordingly, we may be subject to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations related to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA"), applies to the personal data of consumers, business representatives and employees who are California residents, and requires covered businesses to provide specific disclosures in privacy notices and to honor certain requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR") (collectively, "GDPR"), and the Swiss Federal Act on Data Protection impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are generally inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, which could limit our ability to conduct clinical trial activities in the EEA, the UK or elsewhere, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. The United States is also increasingly scrutinizing certain data transfers and may also impose certain data localization requirements, particularly if we transfer personal data to, or process personal data of residents of, high risk or sanctioned jurisdictions.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and, we are, or may become subject to obligations in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR, and the CCPA, require companies to impose specific contractual restrictions on their service providers. Moreover, some clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information.

We publish privacy policies, marketing materials and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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 federal, state and local 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 controlled production, storage, use and disposal of hazardous and flammable materials, including chemicals and biological materials such as infectious agents and various radioactive compounds. 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, as well as our curtailment of the use of these materials or even shutting down our facilities and operations.

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. While we maintain insurance covering our manufacturing facility only, and not our other facilities, for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials, such insurance coverage may not be sufficient to cover extraordinary or unanticipated events at our manufacturing facility.

Risks Related to Our Business and Operations

We are highly dependent on our key personnel, including our President, Chief Executive Officer and Chairman. If we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and particularly on the services of our personnel, including Thomas Zindrick, J.D., our President, Chief Executive Officer and Chairman. We believe that their drug discovery and development experience and overall biopharmaceutical company management experience, would be difficult to replace. Any of our executive officers could leave our employment at any time, as all of our employees are "at-will" employees. We currently do not have "key person" insurance on any of our employees. The loss of the services of our key personnel and any of our other executive officers, key employees, and scientific and medical advisors, and our inability to find suitable replacements, could result in delays in our research and development objectives and harm our business.

Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. We conduct our operations at our facilities in Southern California, a region that is home to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock option grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employee agreements with our key employees, these agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of all of these individuals or the lives of any of our other employees.

We will need to continue to expand the size of our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.*

As of March 31, 2024, we had 23 full-time and part-time employees, including 15 employees engaged in research and development and manufacturing. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and comparable foreign regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize Olvi-Vec, V2ACT Immunotherapy and any other product candidates we develop will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. The services include substantially all aspects of clinical trial management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of Olvi-Vec and our other product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring qualified new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize Olvi-Vec and our other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

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

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Any of the foregoing may materially harm our business, financial condition, results of operations, stock price and prospects.

Unfavorable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations, stock price and prospects.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Public health crises such as pandemics could materially and adversely affect our preclinical studies and clinical trials, business, financial condition and results of operations.

As a result of pandemics and related governmental orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our preclinical studies, clinical trials, business, financial condition and results of operations. Potential disruptions might include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;

- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting health conditions or being forced to quarantine;

- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;

- delays or disruptions in preclinical experiments and studies due to restrictions of on-site staff and unforeseen circumstances at CROs and vendors;

- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;

- interruption of, or delays in receiving, supplies of our product candidates from third-party providers due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;

- limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and preclinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions;

- changes in regulations which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether; and

- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel.

Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition and results of operations.

If our information technology systems or those third parties with whom we work or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work process proprietary, confidential, and sensitive data, including personal data, de-identified health-related data, intellectual property, proprietary business information and trade secrets (collectively, "sensitive information").

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to increase, are becoming increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by artificial intelligence, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, ability to provide our products or services, disruption of clinical trials, loss of data (including data related to clinical trials) and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third parties service providers to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, information technology infrastructure, cloud-based infrastructure, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information technology systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our products. For example, the loss of clinical trial data from completed or 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. Our current security measures may be insufficient to prevent or deter such incidents or interruptions. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop or prevent customers from using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

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 clinical trials and 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.

Our employees, independent contractors, consultants, commercial partners, principal investigators, CMOs, or CROs 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 an FCA case against us even if the government considers the claim unmeritorious and/or declines to intervene, which could require us to incur costs defending against such a claim. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in U.S. federal healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

We have generated significant net operating loss ("NOL") carryforwards and research and development tax credits, and our ability to utilize our net operating loss carryforwards and research and development tax credits to reduce future tax payments may be limited or restricted.

We have generated significant NOL carryforwards and research and development tax credits (R&D credits) as a result of our incurrence of losses and our conduct of research activities since inception. As of December 31, 2023, we had federal and state NOL carryforwards of approximately $160.0 million and $134.0 million, respectively. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. Our U.S. federal NOL carryforwards generated in taxable years beginning before January 1, 2018 can be carried forward to each of the 20 taxable years following the year of the loss. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under current law, U.S. federal NOLs incurred in tax years beginning after December 31, 2017, totaling $50.0 million, may be carried forward indefinitely, but the utilization of such U.S. federal NOLs is limited. As of December 31, 2023, we also had federal and state R&D credit carryforwards of $2.6 million and $2.0 million, respectively. Our U.S. federal R&D credit carryforwards can be carried forward 20 taxable years. If not utilized in that period, these R&D credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under current law, the California state R&D credits carry forward indefinitely until utilized.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and R&D credits to offset its post-change income and taxes, respectively, may be limited. For purposes of these rules, an "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. The application of these rules could limit the amount of NOLs or R&D credit carryforwards that we can utilize annually to offset future taxable income or tax liabilities. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Our NOL and R&D credit carryforwards are subject to review and possible adjustment by U.S. and state tax authorities.

If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

We are required to maintain internal controls over financial reporting. Commencing with our fiscal year ending December 31, 2024, we must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"). This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to our initial public offering ("IPO"), we had never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the U.S. Securities and Exchange Commission (the "SEC"), Nasdaq or other regulatory authorities.

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.

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

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We must design 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. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

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.

Risks Related to Our Common Stock

An active, liquid and orderly trading market for our common stock may not be sustained.

Prior to the closing of our IPO in January 2023, there was no public market for shares of our common stock. An active trading market for our shares may not be sustained. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. As a result of these and other factors, you may be unable to resell your shares of our common stock. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

Our 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.*

We expect our operating results to be subject to quarterly fluctuations, which makes it difficult for us to predict our future operating results. Our net loss and other operating results will be affected by numerous factors, including:

- the timing and cost of, and level of investment in, research and development and commercialization activities relating to our current and any future product candidates, which will change from time to time;
- the total expenses we incur in connection with establishing, equipping, and operating our current and any future manufacturing facility(ies);
- the cost of manufacturing our current and any future product candidates, which may vary depending on the FDA's and comparable foreign regulatory authorities' guidelines and requirements, the quantity of production and the terms of any agreements with suppliers;
- results of preclinical studies and future clinical trials, or the addition or termination of future clinical trials or funding support by us, or future collaborators or licensing partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates;
- changes in accounting pronouncements or changes in our accounting policies;

- changes in the variables used as a basis for valuing these stock-based awards, resulting in changes in the magnitude of the expense that we must recognize; and

- potential unforeseen business disruptions that increase our costs or expenses.

These factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.*

The market price of our common stock has fluctuated, and may continue to fluctuate, widely, due to many factors, some of which may be beyond our control. These factors include, without limitation:

- "short squeezes";

- comments by securities analysts or other third parties, including blogs, articles, message boards and social and other media;

- large stockholders exiting their position in our common stock or an increase or decrease in the short interest in our common stock;

- actual or anticipated fluctuations in our financial and operating results;

- negative public perception of us, our competitors, or the biopharmaceutical and biotechnology industries; and

- overall general market fluctuations.

The stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. In particular, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies have been highly volatile, and we note recent instances of extreme stock price run-ups followed by rapid price declines and stock price volatility seemingly unrelated to company performance following a number of recent initial public offerings, particularly among companies with relatively smaller public floats. For example, the daily closing market price for our common stock has varied significantly since the commencement of trading of our common stock on Nasdaq on January 26, 2023, ranging between a high price of $38.00 on June 21, 2023, and a low price of $5.56 on February 3, 2023. During this time, the price per share of common stock has ranged from an intra-day low of $5.35 per share to an intra-day high of $40.98 per share. Since the closing of our IPO, we have not experienced any material changes in our financial condition or results of operations that would explain such price volatility or trading volume. These broad market fluctuations may adversely affect the trading price of our common stock. In particular, a large proportion of our common stock has been and may continue to be traded by short sellers which has put and may continue to put pressure on the supply and demand for our common stock, further influencing volatility in its market price. Additionally, these and other external factors have caused and may continue to cause the market price and demand for our common stock to fluctuate, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock.

In addition, if the trading volumes of our common shares are low, persons buying or selling in relatively small quantities may easily influence prices of our common shares. This low volume of trades could also cause the price of our common shares to fluctuate greatly, with large percentage changes in price occurring in any trading day session. Holders of our common shares may also not be able to readily liquidate their investment or may be forced to sell at depressed prices due to low volume trading. A decline in the market price of our common shares also could adversely affect our ability to issue additional shares of common shares or other securities and our ability to obtain additional financing in the future. No assurance can be given that an active market in our common shares will develop or be sustained.

The market price for our common stock may be influenced by many factors, including:

- results from, and any delays in, our clinical trial for Olvi-Vec, our preclinical studies and any other future clinical development programs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- 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;
- failure or discontinuation of any of our development programs;
- our ability to commercialize Olvi-Vec and our other product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our partners' and collaborators' ability to successfully commercialize their licensed product candidates;
- developments or setbacks related to drugs that are co-administered with any of our product candidates, such as cellular and targeted therapies;
- 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 the development of Olvi-Vec and any other product candidate we may develop;
- changes in the competitive landscape in our industry, including results of clinical trials of existing and potential future products that compete with Olvi-Vec and our other product candidates;
- our ability to adequately support future growth;
- variations in our financial results or those of companies that are perceived to be similar to us;
- future accounting pronouncements or changes in our accounting policies;
- announcements or expectations of additional financing efforts by us;
- sales of our common stock by us, our insiders or other stockholders;
- recommendations and changes in estimates or recommendations by securities analysts, if any, that cover our stock;

- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad, including bank failures, global pandemics, the Russia/Ukraine conflict or the conflicts in the Middle East; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate rapidly and substantially, including any stock price run-up, regardless of our actual or expected operating performance and financial condition or prospects, which may limit, prevent or make it difficult for prospective investors to assess the rapidly changing value of our common stock or to sell their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

You should not rely on an investment in our common stock to provide dividend income. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur, as the only way to realize any return on their investment.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.

Our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding capital stock, beneficially own shares representing a significant percentage of our common stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. For example, Aladar Szalay, Ph.D. and his affiliated entities have sold a substantial number of shares of our common stock since July 24, 2023, the lock-up agreement expiration date in connection with our IPO.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended (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.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that we will need significant additional capital in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities, and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to our 2022 Equity Incentive Plan (the 2022 Plan) and the 2023 Inducement Plan (the "Inducement Plan"), we are authorized to grant equity awards to our employees, directors and consultants. Additionally, the number of shares of our common stock reserved for issuance under our 2022 Plan will automatically increase on January 1 of each year, beginning on January 1, 2024 and continuing through and including January 1, 2032, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. In addition, pursuant to our Employee Stock Purchase Plan, the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2024 through January 1, 2032, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, and (ii) 2,100,000 shares of common stock; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We are an emerging growth company and a smaller reporting company, and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Tax Act. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from various public company reporting requirements, including being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Quarterly Report, not being required to have our internal control over financial reporting audited by our independent registered public accounting firm under Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our Annual Report on Form 10-K and our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may take advantage of these exemptions until the last day of the fiscal year ending after the fifth anniversary of our IPO (i.e. January 25, 2028) or until we are no longer an emerging growth company, whichever is earlier. We will cease to be an emerging growth company prior to the end of such five-year period if certain earlier events occur, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, our annual gross revenues exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period.

Under the Tax Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period under the Tax Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the Tax Act.

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 are no longer an emerging growth company, which would allow us to take advantage of many of the same exemptions available to emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation. We will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. Investors may 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.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and provisions of Delaware law may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the U.S. federal district courts are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;

- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; and

- any action asserting a claim against us that is governed by the internal affairs doctrine.

This provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may be enforced by a court in those other jurisdictions.

If a court were to find the exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could harm our business, financial condition, results of operations, and prospects. Further, this exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees.

General Risk Factors

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

As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which 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, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Emerging growth companies and smaller reporting companies are exempted from certain of these requirements, but we may 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 obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. 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.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act, the regulations of the Nasdaq Capital Market, the rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Commencing with our fiscal year ending December 31, 2024, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. Prior to our IPO, we had never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We anticipate that the process of building our accounting and financial functions and infrastructure will require significant additional professional fees, internal costs and management efforts. For example, we expect that we will need to implement new systems to enhance and streamline the management of our financial, accounting, human resources and other functions.

However, such systems will likely require us to complete many processes and procedures for the effective use of the systems, which may result in substantial costs. Any disruptions or difficulties in implementing or using these systems could adversely affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations-Recent Accounting Pronouncements."

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act, the Coronavirus Aid, Relief, and Economic Security Act, and the IRA enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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 will rely, 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.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against public companies following declines in the market prices of their securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business.

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

Unregistered Sales of Equity Securities

Warrants

On January 25, 2023, in connection with our IPO, certain warrants issued prior to the IPO were adjusted in accordance with a one for three pre-IPO reverse stock split, enabling the holders to purchase up to an aggregate of 110,975 shares of our Common Stock at an exercise price of $9.00 per share and 3,809 shares of our Common Stock at an exercise price of $10.50 per share (collectively, the "Warrants"). During the first quarter of 2024, holders of the Warrants with an exercise price of $9.00 per share exercised their Warrants for an aggregate of 76,487 shares with the remaining 34,488 Warrants expiring. The Warrants issued with an exercise price of $10.50 per share all expired during the first quarter of 2024.

Use of Proceeds

On January 25, 2023, our Registration Statement on Form S-1, as amended (File No. 333-265828) was declared effective in connection with the IPO of our common stock, pursuant to which we registered an aggregate of 2,500,000 shares of our common stock, of which we sold 2,653,000 shares, including the partial exercise of the underwriters' option to purchase additional shares, at a price to the public of $6.00 per share, for aggregate gross proceeds of $15.9 million. The offering closed on January 30, 2023. The underwriting discounts and commissions for the IPO totaled approximately $1.4 million. We incurred additional costs of approximately $1.9 million in offering expenses, which when added to the underwriting discounts and commissions paid by us, amounts to total fees and costs of approximately $3.3 million. Thus, estimated net offering proceeds to us, after deducting underwriting discounts, commissions and offering expenses, were approximately $12.6 million, including the partial exercise of the underwriters' overallotment option. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10 percent or more of any class of our equity securities or to any other affiliates. The Benchmark Company, LLC and Brookline Capital Markets, a division of Arcadia Securities, LLC, acted as joint book-running managers for the IPO.

As of March 31, 2024, we have used all of the net proceeds from our IPO, primarily to satisfy outstanding accounts payable and working capital. There has been no material change in the planned use of proceeds from our IPO from those disclosed in the final prospectus that forms a part of the Registration Statement filed by us with the SEC pursuant to Rule 424(b) on January 26, 2023.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosure.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-41599), filed with the SEC on January 30, 2023).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-41599), filed with the SEC on January 30, 2023).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-265828), as amended, originally filed with the SEC on August 29, 2022).
4.2	Investors' Rights Agreement, by and among the Registrant and AbbVie, Inc. and Aladar Szalay, Ph.D., dated January 2010 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
4.3	Form of Warrant to Purchase Common Stock issued to WDC Fund I, dated September 2020 (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1, (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
4.4	Form of Umbrella Agreement Regarding Family Investments (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-1, (File No. 333-265828), as amended, originally filed with the SEC on June 24, 2022).
4.5	Form of Convertible Note Purchase Agreement under the Umbrella Agreement (incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-1, (File No. 333-265828), as amended, originally filed with the Commission on June 24, 2022).
4.6	Form of Representative's Warrant (incorporated by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form S-1, (File No. 333-265828), as amended, originally filed with the Commission on September 19, 2022).
4.7	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.8 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-41599), filed with the SEC on May 15, 2023).
4.8	Letter Agreement Amending the Umbrella Agreements, by and among the Registrant and Existing Noteholders dated April 4, 2023 (incorporated by reference to Exhibit 4.10 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-41599), filed with the SEC on May 15, 2023).
4.9	Form of Warrant to Purchase Common Stock issued on July 28, 2023 in connection with Converted Convertible Notes Payable (incorporated by reference to Exhibit 4.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-41599), filed with the SEC on August 14, 2023).
4.10	Form of Warrant to Purchase Common Stock issued on August 1, 2023 in connection with Converted Convertible Notes Payable (incorporated by reference to Exhibit 4.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-41599), filed with the SEC on August 14, 2023).

Exhibit No.	Description
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act, 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, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*†	Certification of Principal Executive Officer and 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 as its XBRL tags are embedded within the Inline XBRL document.
101.SCH**	Inline XBRL Taxonomy Extension Schema.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase.
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document and contained in Exhibit 101).

* Filed herewith.

**Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934 and otherwise are not subject to liability.

† This certification shall not be deemed filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

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.

Date: May 9, 2024

GENELUX CORPORATION

By: */s/ Thomas Zindrick, J.D.*

Thomas Zindrick, J.D.
President, Chief Executive Officer and Chairman
(Principal Executive Officer)

By: */s/ Lourie Zak*

Lourie Zak
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Thomas Zindrick, J.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Genelux Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(r) and 15d-15(r)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2024

By: */s/ Thomas Zindrick, J.D.*
Thomas Zindrick, J.D.
President, Chief Executive Officer and Chairman
(*Principal Executive Officer*)

Exhibit 31.2

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

I, Lourie Zak, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Genelux Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(r) and 15d-15(r) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2024

By: */s/ Lourie Zak*
Lourie Zak
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Thomas Zindrick, J.D., President and Chief Executive Officer of Genelux Corporation (the "Company"), and Lourie Zak, Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2024, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Date: May 9, 2024

/s/ Thomas Zindrick, J.D.	*/s/ Lourie Zak*
Thomas Zindrick, J.D.	Lourie Zak
President, Chief Executive Officer and Chairman	Chief Financial Officer
(Principal Executive Officer)	*(Principal Financial and Accounting Officer)*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Genelux Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.