IOVANCE BIOTHERAPEUTICS, INC.

FORM 10-Q
(Quarterly Report)

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Address	825 INDUSTRIAL ROAD 4TH FLOOR SAN CARLOS, CA, 94070
Telephone	6502607120
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Symbol	IOVA
SIC Code	2836 - Biological Products, (No Diagnostic Substances)
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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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, 2025**

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from __ to __.

Commission File Number 001-36860

IOVANCE BIOTHERAPEUTICS, INC.

(Exact name of issuer as specified in its charter)

Delaware	**75-3254381**
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification number)

825 Industrial Road, Suite 100, San Carlos, CA 94070
(Address of principal executive offices and zip code)

(650) 260-7120
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.000041666	IOVA	The Nasdaq Global Market

As of April 30, 2025, the issuer had 333,934,387 shares of common stock, par value $0.000041666 per share, outstanding.

IOVANCE BIOTHERAPEUTICS, INC.
FORM 10-Q
For the Quarter Ended March 31, 2025

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Forward-Looking Statements and Market Data

This Quarterly Report on Form 10-Q contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements other than statements of historical facts contained in this report are forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "may," "will," "might," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "aim," "potential," "continue," "ongoing," "goal," "forecast," "guidance," "outlook," or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the success, cost, enrollment, and timing of our clinical trials;
- the success, cost, and timing of our product development activities;
- the ability of us or our third-party contract manufacturers to continue to manufacture tumor infiltrating lymphocytes, or TIL, in accordance with our selected process;
- our ability to design, construct, and staff our own manufacturing facility on a timely basis and within the estimated expenses;
- the success of competing therapies that are or may become available;
- regulatory developments in the United States of America, or U.S., and foreign countries;
- the timing of and our ability to obtain and maintain U.S. Food and Drug Administration, or the FDA, European Commission, or other regulatory authority approval of, or other action with respect to, our products and/or product candidates;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- our ability to obtain funding for our operations, including funding necessary to complete further development of our product candidates and commercialization of our products;
- our ability to successfully commercialize Amtagvi® (lifileucel) and Proleukin® (aldesleukin), and any other products and/or product candidates for which we obtain or have obtained FDA or other regulatory approvals, including by the European Commission in the European Union, or the EU;
- the ability and willingness of our third-party research institution collaborators to continue research and development activities relating to our product candidates;
- the potential of our other research and development and strategic collaborations;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our manufacturing methods and products and/or product candidates;
- our plans to research, develop, and commercialize our products and/or product candidates;
- the size and growth potential of the markets for our products and/or product candidates, and our ability to serve those markets;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- fluctuations in the trading price of our common stock; and
- our use of cash and other resources.

Actual results may differ from those set forth in this Quarterly Report on Form 10-Q due to the risks and uncertainties inherent in our business, including those provided in the foregoing list of forward-looking statements and also including, without limitation: the FDA may not agree with our interpretation of the results of our clinical trials; later developments with the FDA that may be inconsistent with already completed FDA meetings; the preliminary clinical results, including efficacy and safety results, from ongoing Phase 2 and Phase 3 clinical trials may not be reflected in the final analyses of these clinical trials including new cohorts within these clinical trials; the results obtained in our ongoing clinical trials, such as the studies and clinical trials referred to in this Quarterly Report on Form 10-Q, may not be indicative of results obtained in future clinical trials or supportive of product approval; regulatory authorities may potentially delay the timing of FDA or other regulatory authority approval of, or other action with respect to, our product candidates, specifically, our description of FDA interactions are subject to the FDA's interpretation, as well as the FDA's authority to request new or additional information; we may not be able to obtain or maintain FDA or other regulatory authority approval of our product candidates; our ability to address FDA or other regulatory authority requirements relating to our clinical programs and registrational plans, such requirements including, but not limited to, clinical and safety requirements, as well as manufacturing and control requirements; risks related to our accelerated FDA review designations; our ability to obtain and maintain intellectual property rights relating to our product pipeline; and the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved.

We caution you that the risks, uncertainties and other factors referenced above may not contain all the risks, uncertainties and other factors that are important to you. In addition, we cannot guarantee future results, level of activity, performance or achievements. Any forward-looking statement made by us in this Quarterly Report on Form 10-Q speaks only as of the date of this Quarterly Report on Form 10-Q or as of the date on which it is made. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether because of new information, future events or otherwise, after the date of this Quarterly Report on Form 10-Q.

Unless the context requires otherwise, in this report the terms "Iovance," the "Company," "we," "us" and "our" refer to Iovance Biotherapeutics, Inc.

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

IOVANCE BIOTHERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(unaudited; in thousands, except share and per share information)

	March 31, 2025	December 31, 2024
ASSETS		
Current Assets		
Cash and cash equivalents	$ 171,668	$ 115,694
Restricted cash	559	—
Trade accounts receivable	70,938	69,340
Short-term investments	188,045	208,087
Inventory	65,545	51,520
Prepaid expenses and other assets	15,894	12,377
Total Current Assets	512,649	457,018
Property and equipment, net	111,584	109,081
Intangible assets, net	285,356	282,398
Operating lease right-of-use assets	50,903	55,201
Restricted cash	5,822	6,359
Long-term assets	426	369
Total Assets	$ 966,740	$ 910,426
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 28,489	$ 27,509
Accrued expenses and other liabilities	84,705	81,936
Note payable - current	1,000	—
Operating lease liabilities	8,499	12,896
Total Current Liabilities	122,693	122,341
Non-Current Liabilities		
Operating lease liabilities – non-current	44,220	44,365
Deferred tax liabilities	31,962	32,315
Long-term note payable	—	1,000
Total Non-Current Liabilities	76,182	77,680
Total Liabilities	198,875	200,021
Commitments and contingencies		
Stockholders' Equity		
Series A Convertible Preferred stock, $0.001 par value; 17,000 shares designated, 194 shares issued and outstanding as of March 31, 2025 and December 31, 2024	—	—
Series B Convertible Preferred stock, $0.001 par value; 11,500,000 shares designated, 1,932,667 and 2,842,158 shares issued and outstanding as of March 31, 2025 and December 31, 2024 respectively	2	3
Common stock, $0.000041666 par value; 500,000,000 shares authorized, 333,934,387 and 305,252,194 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	14	13
Accumulated other comprehensive loss (income)	6,294	(1,046)
Additional paid-in capital	3,262,270	3,095,987
Accumulated deficit	(2,500,715)	(2,384,552)
Total Stockholders' Equity	767,865	710,405
Total Liabilities and Stockholders' Equity	$ 966,740	$ 910,426

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

IOVANCE BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(unaudited; in thousands, except per share information)

	Three Months Ended March 31,	
	2025	2024
Revenue		
Product revenue	**$** 49,324	**$** 715
Total revenue	49,324	715
Costs and expenses		
Cost of sales	$ 49,741	$ 7,261
Research and development	76,879	79,783
Selling, general, and administrative	43,925	31,393
Total costs and expenses	170,545	118,437
Loss from operations	(121,221)	(117,722)
Other income		
Interest and other income, net	3,220	3,338
Net Loss before income taxes	$ (118,001)	$ (114,384)
Income tax benefit	1,838	1,408
Net Loss	$ (116,163)	$ (112,976)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.36)	$ (0.42)
Weighted Average Shares of Common Stock Outstanding, Basic and Diluted	322,868	266,220

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

IOVANCE BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Comprehensive Loss
(unaudited; in thousands)

	Three Months Ended March 31,	
	2025	2024
Net Loss	$ (116,163)	$ (112,976)
Other comprehensive loss:		
Unrealized gain on investments	(110)	(69)
Foreign currency translation adjustment	7,450	(2,341)
Comprehensive Loss	$ (108,823)	$ (115,386)

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

IOVANCE BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Stockholders' Equity
For the Three Months Ended March 31, 2025 and 2024
(unaudited; in thousands, except share information)

	Series A Convertible Preferred Sock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance - December 31, 2024	194	$ —	2,842,158	$ 3	305,252,194	$ 13	$3,095,987	$ (1,046)	$ (2,384,552)	$ 710,405
Stock-based compensation expense	—	—	—	—	—	—	22,970	—	—	22,970
Common stock issued upon purchase of employee stock purchase plan	—	—	—	—	—	—	—	—	—	—
Vesting of restricted shares issued for services	—	—	—	—	3,558,628	—	—	—	—	—
Tax payments related to shares retired for vested restricted stock units	—	—	—	—	(1,387,901)	—	(5,644)	—	—	(5,644)
Common stock issued upon exercise of stock options	—	—	—	—	2,586	—	15	—	—	15
Common stock sold in public and/or at the market offering, net of offering costs	—	—	—	—	25,599,389	1	148,941	—	—	148,942
Common stock issued from preferred stock conversion	—	—	(909,491)	(1)	909,491	—	1	—	—	—
Unrealized gain on investments	—	—	—	—	—	—	—	(110)	—	(110)
Foreign currency cumulative translation adjustment	—	—	—	—	—	—	—	7,450	—	7,450
Net loss	—	—	—	—	—	—	—	—	(116,163)	(116,163)
Balance - March 31, 2025	194	$ —	1,932,667	$ 2	333,934,387	$ 14	$3,262,270	$ 6,294	$ (2,500,715)	$ 767,865
Balance - December 31, 2023	194	$ —	2,842,158	$ 3	256,135,715	$ 11	$2,594,448	$ 2,526	$ (2,012,375)	$ 584,613
Stock-based compensation expense	—	—	—	—	—	—	17,773	—	—	17,773
Vesting of restricted shares issued for services	—	—	—	—	880,242	—	—	—	—	—
Tax payments related to shares retired for vested restricted stock units	—	—	—	—	(315,371)	—	(4,701)	—	—	(4,701)
Common stock sold in public and/or at the market offerings, net of offering costs	—	—	—	—	23,014,000	1	197,360	—	—	197,361
Common stock issued upon exercise of stock options	—	—	—	—	41,753	—	364	—	—	364
Unrealized gain on investments	—	—	—	—	—	—	—	(69)	—	(69)
Foreign currency cumulative translation adjustment	—	—	—	—	—	—	—	(2,341)	—	(2,341)
Net loss	—	—	—	—	—	—	—	—	(112,976)	(112,976)
Balance - March 31, 2024	194	$ —	2,842,158	$ 3	279,756,339	$ 12	$2,805,244	$ 116	$ (2,125,351)	$ 680,024

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

IOVANCE BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Cash Flows
(unaudited; in thousands)

	Three Months Ended March 31,	
	2025	**2024**
Cash Flows from Operating Activities		
Net loss	$ (116,163)	$ (112,976)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	22,915	17,178
Unrealized foreign exchange gains	59	(96)
Amortization of intangible assets	5,406	4,633
Amortization of right of use asset	2,870	2,296
Depreciation and amortization of property and equipment	2,789	2,978
Deferred tax benefit	(1,838)	(1,408)
Accretion of discounts and premiums on investments	(2,146)	(2,335)
Loss on asset disposals	44	—
Changes in assets and liabilities:		
Prepaid expenses, other assets and long-term assets	(3,251)	5,888
Trade accounts receivable	(1,598)	(83)
Inventory	(13,970)	(6,735)
Operating lease liabilities	(3,113)	(2,789)
Accounts payable	2,052	(5,815)
Accrued expenses and other liabilities	2,250	(23,015)
Net cash used in operating activities	(103,694)	(122,279)
Cash Flows from Investing Activities		
Maturities of investments	120,000	87,000
Purchase of investments	(97,922)	(141,762)
Cash paid for acquisition, including contingent consideration, net of cash acquired	—	(52,573)
Purchase of property and equipment	(6,211)	(4,171)
Net cash used in investing activities	15,867	(111,506)
Cash Flows from Financing Activities		
Tax payments related to shares withheld for vested restricted stock units	(5,644)	(4,701)
Proceeds from the issuance of common stock upon exercise of options	15	364
Proceeds from the issuance of common stock, net	148,944	197,913
Net cash provided by financing activities	143,315	193,576
Effect of foreign exchange rate changes	508	(491)
Net increase in cash, cash equivalents and restricted cash	55,996	(40,700)
Cash, Cash Equivalents and Restricted Cash Beginning of Period	122,053	181,318
Cash, Cash Equivalents and Restricted Cash End of Period	$ 178,049	$ 140,618
Supplemental disclosure of non-cash investing and financing activities:		
Net unrealized loss on investments	110	69
Acquisition of property and equipment included in accounts payable and accrued expenses	6,491	683
Intangible asset and deferred tax liability arising from contingent consideration	—	17,495
Accrued offering costs in accounts payable and accrued expenses	—	552
Conversion of convertible preferred stock to common stock	1	—
Increase / (decrease) in lease liabilities due to obtaining/(reduction) in right-of-use assets from lease modifications	(1,429)	11,297

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

IOVANCE BIOTHERAPEUTICS, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

NOTE 1. GENERAL ORGANIZATION, BUSINESS AND LIQUIDITY

General Organization and Business

Iovance Biotherapeutics, Inc. (the "Company") is a commercial-stage biopharmaceutical company pioneering a transformational approach to treating cancer by harnessing the human immune system's ability to recognize and destroy diverse cancer cells using therapies personalized for each patient. The Company's mission is to be the global leader in innovating, developing and delivering tumor infiltrating lymphocyte ("TIL") cell therapies for patients with solid tumor cancers. The Company is executing the U.S. launch of Amtagvi® (lifileucel), the first product within its autologous TIL cell therapy platform, while also marketing Proleukin® (aldesleukin), an interleukin-2 ("IL-2") product used in the Amtagvi® treatment regimen and in other applications. Amtagvi® is the first and the only one-time, individualized T cell therapy to receive U.S. Food and Drug Administration ("FDA") approval for a solid tumor cancer. Amtagvi® is a tumor-derived autologous T cell immunotherapy indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. This indication was approved under accelerated approval based on overall response rate ("ORR"). Continued approval for this indication may be contingent upon verification and description of clinical benefit in future confirmatory trials. Amtagvi® and Proleukin® are part of a treatment regimen that includes lymphodepletion.

Beyond the U.S., the Company plans to launch Amtagvi® into additional markets with a high prevalence of advanced melanoma, including the European Union ("EU"), United Kingdom ("UK"), Canada, Switzerland, and Australia. In June 2024, the Company submitted a centralized marketing authorization application ("MAA") to the European Medicines Agency ("EMA") for lifileucel. In August 2024, the MAA was validated and accepted for review by the EMA. In October 2024, an MAA was submitted to the Medicines and Healthcare products Regulatory Agency in the UK. A new drug submission ("NDS") was deemed eligible for Notice of Compliance with Conditions ("NOC/c") by Health Canada and submitted in December 2024 and then accepted in January 2025. The NOC/c policy includes a prioritized 200-day review process for potential NDS approval in mid-2025. If approved, lifileucel is expected to be the first and only approved therapy in this treatment setting in these markets. Across the U.S. and other targeted global markets, Amtagvi® has the potential to address more than 20,000 previously treated advanced melanoma patients annually.

The Company was founded to build upon the promise of TIL cell therapy that was previously demonstrated in single-center clinical trials at academic research centers, including the National Cancer Institute ("NCI"). The Company's multi-center trials, novel TIL products, manufacturing processes, facilities, and bioanalytical platforms have transformed TIL cell therapy into a commercially viable treatment which thousands of patients with cancer can access.

The Company manufactures Amtagvi® and its investigational TIL cell therapies using centralized, scalable, and proprietary manufacturing processes which rejuvenate and multiply polyclonal T cells unique to each patient into the billions and yields a cryopreserved, individualized therapy. Amtagvi® is manufactured for commercial use at the Company's manufacturing facility, the Iovance Cell Therapy Center (the "*i*CTC"), and by a contract manufacturing organization ("CMO").

The Company's development pipeline includes multicenter trials of TIL cell therapies in additional treatment settings and indications for solid tumor cancers. To potentially improve outcomes for patients, the Company is investigating TIL monotherapies for patients previously treated with standard of care therapies and TIL cell therapy in combination with standard of care therapies for patients in earlier treatment settings. The Company is conducting two ongoing registrational trials to support a supplementary BLA ("sBLA"), of lifileucel in frontline advanced melanoma and in advanced non-small cell lung cancer ("NSCLC") following standard of care chemo-immunotherapy. The Company is also developing next generation therapies, such as genetically modified TIL cell therapy and next generation cytokines for use in the TIL cell therapy regimen.

Basis of Presentation of Unaudited Condensed Consolidated Financial Information

The accompanying unaudited condensed consolidated financial statements of the Company for the three months ended March 31, 2025 and 2024 have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP") for interim financial information and pursuant to the requirements for reporting on Form 10-Q and Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for audited financial statements. However, such information reflects all adjustments (consisting solely of normal recurring adjustments), which are, in the opinion of management, necessary for the fair

presentation of the Company's financial position and results of operations. Results shown for interim periods are not necessarily indicative of the results that may be expected for the year ended December 31, 2025 or for any other period. The condensed consolidated balance sheet as of December 31, 2024 was derived from the audited consolidated financial statements included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on February 27, 2025.

Liquidity

As of March 31, 2025, the Company had $366.1 million in cash, cash equivalents, short term-investments, and restricted cash ($171.7 million of cash and cash equivalents, $188.0 million in short-term investments, and $6.4 million in restricted cash). The Company has recently launched its first internally developed commercial product and continues to be engaged in the development of therapeutics to fight cancer, specifically solid tumors. With the recent approval of the Biologics License Application ("BLA"), the Company began to generate revenue from the sale of its product Amtagvi® in the second quarter of 2024. Furthermore, following the acquisition of the worldwide rights to Proleukin® (as discussed below in Note 4 - Proleukin® Acquisition) in 2023, the Company began to generate revenue from the sales of Proleukin®. However, such revenues for Amtagvi® and Proleukin® may not be material enough to generate positive operational cash flows during the 12 months from the date the condensed consolidated financial statements are issued and this Form 10-Q is filed. The Company has incurred a net loss of $116.2 million for the three months ended March 31, 2025 and used $103.7 million of cash in its operating activities during the three months ended March 31, 2025.

The Company expects to continue to incur significant expenses to support its execution of the commercial launch of Amtagvi®, fund ongoing clinical programs, including its NSCLC registrational study, IOV-LUN-202, and its frontline advanced melanoma Phase 3 confirmatory trial, TILVANCE-301, continue the development of its pipeline candidates, and for other general corporate purposes. Based on the funds the Company has available as of the date these condensed consolidated financial statements are issued, the Company believes that it has sufficient capital to fund its anticipated operating expenses and capital expenditures as planned for at least the next twelve months from the date these condensed consolidated financial statements are issued.

Concentrations of Risk

The Company is subject to credit risk from its portfolio of cash, cash equivalents, trade accounts receivable and investments. Under its investment policy, the Company limits amounts invested in securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. The Company does not believe it is exposed to any significant concentrations of credit risk from these financial instruments. The goals of its investment policy are safety and preservation of principal, diversification of risk, and liquidity of investments sufficient to meet cash flow requirements.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash, Cash Equivalents, and Investments

The Company's cash and cash equivalents include short-term investments with original maturities of three months or less when purchased. The Company's investments are classified as "available-for-sale." The Company includes these investments in current assets or non-current assets in the condensed consolidated balance sheets based on the length of maturity from the reporting date and carries them at fair value. Unrealized gains and losses on available-for-sale securities are recorded in accumulated other comprehensive loss. Impairment losses related to credit losses (if any) are recorded as an allowance for credit losses with an offsetting entry to Interest and other income, net. No impairment losses related to credit losses were recognized for the three months ended March 31, 2025 and 2024. The cost of debt securities is adjusted for the amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in Interest and other income, net in the condensed consolidated statements of operations. Gains and losses on securities sold are recorded based on the specific identification method and are included in Interest and other income, net in the condensed consolidated statements of operations. The Company has not incurred any realized gains or losses from sales of securities to date. The Company's investment policy limits investments to certain types of instruments such as certificates of deposit, money market instruments, obligations issued by the U.S. government and U.S. government agencies as well as corporate debt securities and commercial paper, and places restrictions on maturities and concentration by type and issuer, except for securities issued by the U.S. government.

Restricted Cash

As of March 31, 2025 and December 31, 2024, restricted cash totaled $6.4 million. These amounts have been classified as either current or non-current assets in the Company's condensed consolidated balance sheet based on the maturity date of the underlying letter of credit agreement.

The Company maintains a required minimum balance in segregated bank accounts in connection with its letters of credit for which amounts are restricted as to their use by the Company. As of March 31, 2025, the Company's letters of credit were primarily comprised of a letter of credit for the benefit of the *i*CTC used as a security deposit for the lease in the amount of $5.45 million and a letter of credit for $0.6 million for the benefit of the landlord for the Company's headquarters lease (See Note 13 - Leases). The letter of credit for $5.45 million originally expired on May 28, 2020, however, it automatically extends for additional one-year periods, without written agreement, to May 28 in each succeeding calendar year, through at least 60 days after the lease expiration date. Further, on the expiration of the seventh year of the lease, and each anniversary date thereafter, the letter of credit may be decreased by $1.0 million, with a minimum security deposit of $1.5 million maintained through the end of the lease term. The letter of credit with the landlord for the Company's headquarters lease expires on February 1, 2032, however, it will be automatically extended, without written agreement, for one-year periods to February in each succeeding calendar year.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash, reported within the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows (in thousands):

	March 31,	
	2025	2024
Cash and cash equivalents	$ 171,668	$ 134,188
Restricted cash	6,381	6,430
Total cash, cash equivalents and restricted cash	$ 178,049	$ 140,618

Asset Acquisitions

The Company evaluates acquisitions of assets using the guidance in Accounting Standard Codification ("ASC") Topic 805, *Business Combinations* ("ASC 805"), to determine whether the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to assess if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further assessment is required to determine whether the Company has acquired inputs and processes that have the ability to create outputs, which would meet the requirements of a business.

If the assets acquired do not constitute a business, the Company accounts for asset acquisitions using the cost accumulation and allocation method. Under this method, the cost of the acquisition, including direct acquisition-related costs, is allocated to the assets acquired on a relative fair value basis. Goodwill is not recognized in an asset acquisition and any difference between consideration transferred and the fair value of the net assets acquired is allocated to the identifiable assets acquired based on their relative fair values.

Deferred tax liabilities arising from basis differences in assets acquired are calculated using the simultaneous equations method under ASC Topic 740, *Income Taxes* ("ASC 740"), and based on the effective tax rate. The resulting deferred tax liability is recorded in the condensed consolidated balance sheet as of March 31, 2025 and December 31, 2024.

Contingent consideration in the scope of ASC Topic 815, *Derivatives and Hedging* ("ASC 815"), is included in the cost of the asset acquisition at its acquisition date fair value. Contingent consideration in the scope of ASC Topic 450, *Contingencies* ("ASC 450"), is recognized when it is both probable and reasonably estimable.

Inventory and Cost of Sales

Inventory is stated at the lower of cost or net realizable value on a first-in, first-out basis. Cost includes amounts related to materials, internal labor, costs of external manufacturing, and allocable depreciation of manufacturing facilities, equipment and overhead. Net realizable value is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation. Inventoriable costs incurred, such as manufacturing costs incurred prior to regulatory approval that did not qualify for capitalization and clinical manufacturing costs, are expensed as incurred as research and development expenses.

Upon the February 2024 approval of Amtagvi®, the Company began capitalizing inventory and manufacturing costs for the commercial manufacturing of Amtagvi®. Additionally, inventory that initially qualifies for capitalization but that may ultimately be used for the production of clinical drug product or utilized in research and development programs is expensed as research and development expense when it has been designated for the manufacture of clinical drug product or use in research and development activities.

Proleukin® inventories presented in the condensed consolidated balance sheet as of March 31, 2025 include a step-up of the fair value of inventories as a result of the acquisition of the worldwide rights to Proleukin®.

The Company periodically reviews inventory for excess and obsolescence, considering factors such as its most recent sales forecast compared to quantities on hand and the expiration date of the product and materials. The Company adjusts its inventory that is obsolete or otherwise unmarketable to its estimated net realizable value in the period in which the impairment is first identified. Any such adjustments are included as a component of cost of sales within the Company's condensed consolidated statements of operations.

Cost of sales includes inventory and period costs related to overhead and manufacturing costs of Amtagvi® during the three month period ended March 31, 2025 and during the period from approval through March 31, 2024, as well as the cost of inventories and other costs that are directly associated with the purchase and sales of Proleukin®. In addition, cost of sales in the Company's condensed consolidated statements of operations includes royalties payable on sales of its products, as well as non-cash expenses including amortization of the fair value step-up of acquired Proleukin® inventory which is recognized as the acquired inventory units are sold, the acquired intangible asset related to developed technology, and the intellectual property license intangible assets.

During the Company's commercial manufacturing process, certain Amtagvi® product may become out-of-specification, meaning they fall outside commercial specifications. This out-of-specification product can still be utilized by patients in a clinical trial, an expanded or early access program, or single-patient investigational new drug, at which point the costs associated with these batches are classified as research and development expense based on the fact that the Company receives clinical data related to these infusions.

Trade Accounts Receivable

Trade accounts receivable are recorded net of allowances for product returns and estimated credit losses. The estimate of allowance for credit losses considers factors, including existing contractual payment and the aging of receivable from its customers. To date, the Company has determined that an allowance for credit losses is not required.

Intangible Assets

The Company's intangible assets are initially measured based on an allocation of the cost of the acquisition to the assets acquired on a relative fair value basis and are recorded net of accumulated amortization, while intangible assets recorded as the result of milestone or license payments are recorded at the amount paid. The Company amortizes the intangible assets on a straight-line basis over their estimated useful lives.

When contingent consideration is a component of the cost of an asset acquisition, the Company capitalizes the amount of incremental cost from the contingent consideration related to the intangible asset acquired in the period the underlying contingency is resolved. When this occurs, the Company will recognize amortization expense on the incremental cost prospectively from the date the incremental costs are capitalized.

The Company reviews intangible assets for impairment at least annually and whenever events or changes in circumstances have occurred which could indicate that the carrying value of the assets are not recoverable. If such indicators are present, the Company assesses the recoverability of affected assets by determining if the carrying value of the assets is less than the sum of the undiscounted future cash flows of the assets. If the assets are found to not be recoverable, the Company measures the amount of impairment by comparing the carrying value of the assets to their fair values. The Company determined that no indicators of impairment existed as of March 31, 2025.

Leases

The Company determines if an arrangement includes a lease at inception and thereafter, if modified. Operating leases are included in its condensed consolidated balance sheets as operating lease right-of-use assets and operating lease liabilities as of March 31, 2025 and December 31, 2024. Operating lease right-of-use assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date or modification date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses an estimated incremental borrowing rate that is applicable to the Company based on the information available at the later of the lease commencement or modification date.

The operating lease right-of-use assets also include any lease payments made less lease incentives. The Company's leases may include options to extend or terminate the lease, which is considered in the lease term when it is reasonably certain that the Company will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term and recorded in costs and expenses in the condensed consolidated statements of operations. The Company has elected not to apply the recognition requirements of Accounting Standards Update ("ASU") No. 2016-02 and No. 2018-10 (together "Topic 842") for short-term leases.

For lease agreements entered into by the Company that include lease and non-lease components, such components are generally accounted for separately.

Revenue Recognition

The Company recognizes revenue from product sales in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price using the most likely method based on historical experience, as well as applicable information currently available.

In the U.S., products are sold principally to hospitals and clinics, as well as distributors and wholesalers, and outside of the U.S. to hospitals and clinics. Contractual performance obligations are usually limited to transfer of control of the product to the customer. In the case of Amtagvi®, revenue is recognized upon infusion while for Proleukin®, transfer of control occurs either upon shipment or upon receipt of the product after considering when the customer obtains legal title to the product. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring its products and is generally based on a list of fixed prices less allowances for chargebacks, product returns, rebates and discounts. The Company's payment terms to customers range from 45 to 105 days; payment terms differ by customer and by product.

Revenue is reduced at the time of recognition for expected chargebacks, product returns, discounts, rebates, and sales allowances, collectively referred to as gross to net adjustments ("GTN adjustments"). In the U.S., these GTN adjustments are attributable to various commercial arrangements and government programs. In addition, non-U.S. government programs include different pricing schemes such as cost caps and volume discounts. Cash discounts are recorded as a reduction to receivables and settled through the issuance of credits, typically within one month. All other GTN adjustments are recorded as a liability and settled through cash payments to the customer.

Significant judgment is required in estimating GTN adjustments considering legal interpretations of applicable laws and regulations, historical experience, payer channel mix, current contract prices under applicable programs, processing time lags and inventory levels in the distribution channel.

Indirect taxes collected from customers and remitted to government authorities that are related to sales of the Company's products, primarily in Europe, are excluded from revenues.

Stock-Based Compensation

The Company periodically grants stock options to employees and non-employees as compensation for services rendered. The Company accounts for all stock-based payment awards made to employees, including the employee stock purchase plans, and non-employees in accordance with the authoritative guidance provided by the Financial Accounting Standards Board ("FASB") where the value of the award is measured on the date of grant and recognized over the vesting period. Forfeitures are recognized in the period in which they occur. The Company accounts for stock option grants to non-employees in a similar manner as stock option grants to employees except for the term used in the grant date fair value, therefore no longer requiring a re-measurement at the then-current fair values at each reporting date until the shares underlying the options have vested. The non-employee awards that contain a performance condition that affects the quantity or other terms of the award are measured based on the outcome that is probable.

The fair value of the Company's common stock option grants is estimated using a Black-Scholes option pricing model, which uses certain assumptions related to risk-free interest rates, expected volatility, expected term of the common stock options, and future dividends. The stock-based compensation expense is recorded based upon the value derived from the Black-Scholes option pricing model. The assumptions used in the Black-Scholes option pricing model could affect compensation expense recorded in future periods.

The Company issues restricted stock units ("RSUs") from time to time as part of its equity incentive plans. The Company measures the compensation cost with respect to RSUs issued to employees based upon the estimated fair value of the equity instruments at the date of the grant, which is recognized as an expense over the period during which an employee is required to provide services in exchange for the awards. The fair value of RSUs is based on the closing price of the Company's common stock on the grant date. In addition to RSUs that have time-based vesting requirements, from time to time the Company may issue RSUs that include certain performance vesting criteria based upon the satisfaction of stated objectives ("PRSUs"). The Company measures the compensation cost with respect to PRSUs issued to employees based upon the estimated fair value of the equity instruments at the date of grant, which is recognized as an expense over the period that achievement is determined to be probable through the stated service period associated with the award.

Accrued Research and Development Costs

Research and development costs are expensed as incurred. Clinical development costs compose a significant component of research and development costs. The Company has a history of contracting with third parties, including contract research organizations ("CROs"), independent clinical investigators, and contract manufacturing organizations ("CMOs") that perform various clinical trial activities on the Company's behalf in connection with the ongoing development of the Company's product candidates. The financial terms of these contracts are subject to negotiations and may vary from contract to contract and may result in uneven payment flow. The Company accrues and expenses costs for clinical trial activities performed by third parties based upon the work completed to date for each clinical trial in accordance with agreements established with CROs, hospitals, and clinical investigators. Accruals for CROs and CMOs are recorded based on services received and efforts expended pursuant to agreements established with CROs, CMOs and other outside service providers. The Company determines its costs through discussions with internal clinical stakeholders and outside service providers as to the progress or stage of completion of clinical trials or services and the contracted fee to be paid for such services.

Included in the Company's clinical development costs are investigator costs, which are costs associated with treatments administered at clinical sites as required under each clinical trial protocol. The Company's determination of clinical investigator costs and related timing of expense recognition will depend on a number of factors that include, but are not limited to, (i) the overall number of patients that enroll in the trial at each individual site, (ii) the length of clinical trial enrollment period, (iii) discontinuation and completion rates of patients, (iv) duration of patient safety follow-ups, (v) the number of sites included in the clinical trial, and (vi) the contracted fee of each participating site for patient treatment while on clinical trial, which can vary greatly for several reasons including, but not limited to, geographic region, medical center or physician costs, and overhead costs. In addition, the Company's estimates for per patient trial costs will vary based on a number of factors that include, but are not limited to, the extent of additional procedures that may be administered by investigators as a result of patient health status, recoverability of patient costs through insurance carriers of patients, and unanticipated cost of injuries incurred as a result of the clinical trial treatment. The Company accrues estimated expenses resulting from obligations under investigator site agreements as the timing of payments does not always timely align with the periods over which the treatments are administered by the clinical investigators. These estimates are typically based on contracted amounts, patient visit data, discussions with internal clinical stakeholders and outside service providers, and historical look-back analysis of actual payments made to date.

The Company makes judgements and estimates in determining the accrual balance in each reporting period.

In the event advance payments are made to a CRO, CMO or other outside service provider, the payments are recorded within prepaid expenses and other current assets in the condensed consolidated balance sheets and subsequently recognized as research and development expense in the condensed consolidated statements of operations when the associated services have been performed. As actual costs become known, the Company adjusts its estimates, liabilities and assets. Inputs used in the determination of estimates discussed above may vary from actual, which will result in adjustments to research and development expense in future periods.

Selling, general, and administrative expense

Selling, general and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, procurement, legal, investor relations, facilities, business development, marketing, commercial, information technology and human resources functions. Other significant costs include facility costs not otherwise capitalized in inventory or included in research and development expenses. Selling, general and administrative costs are expensed as incurred, and the Company accrues for services provided by third parties related to such expenses by monitoring the status of services provided and receiving estimates from its service providers and adjusting its accruals as actual costs become known.

Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period.

Diluted net loss per share is computed by dividing the net loss by the sum of the weighted average number of shares of common stock outstanding and the dilutive common stock equivalent outstanding during the period. The Company's potentially dilutive common stock equivalent shares, which include incremental common shares issuable upon (i) the exercise of outstanding stock options, (ii) purchases through the 2020 Employee Stock Purchase Plan (the "2020 ESPP"), (iii) vesting of restricted stock units, and (iv) conversion of preferred stock, are only included in the calculation of diluted net loss per share when their effect is dilutive.

As of March 31, 2025 and 2024, the following outstanding common stock equivalents have been excluded from the calculation of net loss per share because their impact would be anti-dilutive:

	March 31,	
	2025	2024
Stock options	18,798,667	18,697,395
Restricted stock units	12,160,195	12,080,735
Employee Stock Purchase Plan	367,096	296,751
Series A Convertible Preferred Stock*	97,000	97,000
Series B Convertible Preferred Stock*	1,932,667	2,842,158
	33,355,625	34,014,039

** on an as-converted basis. (See Note 10 – Stockholders' Equity)*

The dilutive effect of potentially dilutive securities would be reflected in diluted earnings per common share by application of the treasury stock method. Under the treasury stock method, an increase in the fair market value of the Company's common stock could result in a greater dilutive effect from potentially dilutive securities.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to such estimates and assumptions include assumptions made in the fair value of intangible assets, inventories acquired as part of the acquisition of Proleukin®, equity awards and related stock-based compensation, assumptions used in measuring operating right-of-use assets and operating lease liabilities, accounting for potential liabilities, including estimates inherent in accruals related to clinical trials, and the realizability of the Company's deferred tax assets.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Iovance Biotherapeutics, Inc. and its wholly-owned subsidiaries, Iovance Biotherapeutics Manufacturing LLC, Iovance Biotherapeutics GmbH, Iovance Biotherapeutics B.V., Iovance Biotherapeutics UK Ltd, Iovance Biotherapeutics UK SP Ltd, Iovance Biotherapeutics Canada, Inc., and Iovance Australia Pty Ltd. All intercompany accounts and transactions have been eliminated.

Foreign Currency Translation

The condensed consolidated financial statements are presented in U.S. dollars, which is the Company's reporting currency. The assets and liabilities of the Company's subsidiaries whose functional currencies are not in U.S. dollars are translated into U.S. dollars at the related period-end exchange rate. The U.S. dollar effects that arise from translation of net assets of these subsidiaries at changing rates are recognized in accumulated other comprehensive loss in the condensed consolidated balance sheets. The subsidiaries' net loss is translated into U.S. dollars by using the average exchange rate for the applicable period.

Segment Reporting

The Company operates in one segment, focused on innovating, developing and commercializing therapies using autologous TIL for patients with solid tumor cancers. See Note 11 – Segment Information.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis. Early adoption and retrospective reporting are permitted. The Company is currently evaluating the impact of ASU 2023-09 on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires the disaggregation of certain expense captions into specified categories in disclosures within the notes to the financial statements to provide enhanced transparency into the expense captions presented on the face of the income statement. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026 and interim periods beginning after December 15, 2027, with early adoption permitted, and may be applied either prospectively or retrospectively to financial statements issued for reporting periods after the effective date of ASU 2024-03 or retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating the impact of adopting ASU 2024-03.

NOTE 3. CASH EQUIVALENTS AND INVESTMENTS

The amortized cost and fair value of cash equivalents and investments as of March 31, 2025 and December 31, 2024 were as follows (in thousands):

As of March 31, 2025	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 204,951	$ 7	$ —	$ 204,958
Money market funds	107,250	—	—	107,250
Total investments	$ 312,201	$ 7	$ —	$ 312,208

As of December 31, 2024	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 207,970	$ 117	$ —	$ 208,087
Money market funds	61,432	—	—	61,432
Total investments	$ 269,402	$ 117	$ —	$ 269,519

The fair value of cash equivalents and investments as of March 31, 2025 and December 31, 2024, are classified as follows in the Company's condensed consolidated balance sheets (in thousands):

Classified as:	March 31, 2025	December 31, 2024
Cash equivalents	$ 124,163	$ 61,432
Short-term investments	188,045	208,087
Total investments	$ 312,208	$ 269,519

Cash equivalents in the tables above exclude cash demand deposits of $47.5 million and $54.3 million as of March 31, 2025 and December 31, 2024, respectively. Unrealized gains and losses are included in accumulated other comprehensive loss, and as of March 31, 2025 and December 31, 2024, no unrealized losses on available-for-sale securities have resulted from credit risk. All available-for-sale securities held as of March 31, 2025 and December 31, 2024 had contractual maturities of less than one year. No significant available-for-sale securities held as of the periods presented have been in a continuous unrealized loss position for more than 12 months. To date, the Company has not recorded any impairment charges on its investments.

Recurring Fair Value Measurements

As of March 31, 2025, and December 31, 2024, the fair value of the Company's financial assets that are measured at fair value on a recurring basis, which consist of cash equivalents and short-term and long-term investments classified as available-for-sale securities, are categorized in the table below based upon the lowest level of significant input to the valuations (in thousands):

	Assets at Fair Value as of March 31, 2025			
	Level 1	Level 2	Level 3	Total
U.S. treasury securities	$ 204,958	$ —	$ —	$ 204,958
Money market funds	107,250	—	—	107,250
Total investments	$ 312,208	$ —	$ —	$ 312,208

	Assets at Fair Value as of December 31, 2024			
	Level 1	Level 2	Level 3	Total
U.S. treasury securities	$ 208,087	$ —	$ —	$ 208,087
Money market funds	61,432	—	—	61,432
Total	$ 269,519	$ —	$ —	$ 269,519

NOTE 4. PROLEUKIN® ACQUISITION

On January 23, 2023, the Company and its wholly owned subsidiary, Iovance Biotherapeutics UK Ltd (the "Purchaser") entered into an Option Agreement (the "Option Agreement") with Clinigen Holdings Limited, Clinigen Healthcare Limited, and Clinigen, Inc. (collectively, "Clinigen"), a global pharmaceutical services company, pursuant to which the Purchaser would acquire the worldwide rights for the manufacturing, supply, commercialization and sale of Proleukin® (aldesleukin) (the "Acquisition").

On May 18, 2023, the Company completed the Acquisition and specifically acquired (i) all issued and outstanding shares of Clinigen SP Limited (the "Target"), (ii) the business of the Target and Clinigen (the "Proleukin® Business") comprising the manufacturing, supply, commercialization and the generation of income from the Product rights and the undertaking of an active role in the development, maintenance and exploitation of those rights, and (iii) certain specified assets identified in the Option Agreement. Pursuant to the Option Agreement, the Company paid to Clinigen (i) an upfront payment of £166.9 million (or approximately $207.2 million), including the applicable stamp-tax payment, and (ii) a payment for certain inventory of £2.4 million (or approximately $3.0 million) using existing cash on hand. The Option Agreement includes potential future contingent payments, as discussed below.

The Acquisition was accounted for as an asset acquisition because substantially all of the fair value of the acquired assets was concentrated in the acquired developed technology related to the intellectual property rights of Proleukin® and therefore the Acquisition does not meet the definition of a business in accordance with ASC 805. The Proleukin® Business operations have been included in the Company's condensed consolidated financial statements commencing from the acquisition date.

The following table summarizes the total cash consideration and allocated acquisition date fair values of assets acquired and liabilities assumed at the time of the acquisition (in thousands):

		Amounts
Cash	$	35
Inventory		9,688
Developed technology		232,665
Assembled workforce		636
Deferred tax liability		(20,352)
Total Cost of Acquisition	$	222,672

The $222.7 million of total cost of the Acquisition consisted of (i) a $210.2 million of cash payment to Clinigen and (ii) $12.5 million of direct transaction costs incurred by the Company. The Option Agreement additionally provides for contingent cash payments consisting of (i) a milestone payment of £41.7 million, or $52.6 million, upon first approval of lifileucel in advanced melanoma, (ii) deferred consideration based on double digit rates on global net sales (as defined in the Option Agreement) payable from the Company to the sellers following the completion of the Acquisition over a deferred consideration term of twelve years, and (iii) after the deferred consideration term, earnout payments payable from the Company to sellers following the completion of the transaction if deferred consideration payments are equal or greater than the deferred consideration amount provided for in the Option Agreement. These contingent payments were determined to be within the scope of ASC 450 and will be recognized when they are both probable and estimable. During the first quarter of 2024, the Company made the required milestone payment of $52.6 million (£41.7 million) upon the approval of the Company's BLA of Amtagvi®, which was capitalized as an intangible asset and is being amortized over the remaining useful life of such asset. Additionally, $17.5 million (£13.9 million) was added to the carrying value of the acquired developed technology intangible asset, which reflects the deferred tax liability recognized on the temporary differences related to the book and tax basis of the acquired intangible assets.

The net assets acquired in the Acquisition were recorded by allocating the total cost of the Acquisition to the assets acquired on a relative fair value basis based on their estimated fair values as of May 18, 2023, which is the date that the Acquisition was completed.

The fair value of the developed technology was estimated using a multi-period excess earnings income approach that discounts expected cash flows to present value by applying a discount rate that represents the estimated rate that market participants would use to value the intangible assets. The fair value of the developed technology is being amortized over an expected useful life of 15 years and is recorded as Cost of Sales in the Company's condensed consolidated statement of operations.

The fair value of the assembled workforce was estimated using a replacement cost less depreciation method. The fair value of the assembled workforce is being amortized over an expected useful life of 3 years and is recorded as selling, general and administrative expense in the Company's condensed consolidated statement of operations.

The weighted average amortization period the developed technology and assembled workforce is 14.8 years.

The fair value of the acquired inventory was determined using the comparative sales method of the market approach, which uses historical and expected average selling prices of inventory as the base amount to which adjustment for costs to complete for work-in-process, cost of disposal and reasonable profit allowance are applied. The inventory fair value adjustment is being amortized as cost of sales as the acquired inventories are sold.

A deferred tax liability was recognized on the temporary differences related to the book and tax basis of the acquired intangible assets. The deferred tax liability and resulting adjustment to the carrying amount of the acquired intangibles was calculated using the simultaneous equations method under ASC 740. The tax rate used is based on the estimated statutory rates in the UK as this is where the intangible assets are domiciled.

NOTE 5. INTANGIBLE ASSETS, NET

The gross carrying amounts and net book value of intangible assets as of March 31, 2025 and December 31, 2024, are as follows (in thousands):

	March 31, 2025	December 31, 2024
Developed technology	$ 314,097	$ 304,939
Assembled workforce	662	643
Intellectual property license	7,500	7,500
Patents	225	—
Total intangible assets	$ 322,484	$ 313,082
Less: accumulated amortization	(37,128)	(30,684)
Intangible assets, net	$ 285,356	$ 282,398

The Company recognized amortization expense of $5.4 million during the three months ended March 31, 2025 and $4.6 million for same period ended March 31, 2024. Amortization expense for the developed technology and the intellectual property license intangible assets is recorded in cost of sales, amortization expense for the assembled workforce is recorded in selling, general and administrative expense, and amortization expense for the patents is recorded in research and development expense in the condensed consolidated statement of operations for the three months ended March 31, 2025, and 2024.

The total estimated amortization of the Company's intangible assets for the remainder of the year ending December 31, 2025, and the years ending December 31, 2026, 2027, 2028, and 2029 are $16.6 million, $22.0 million, $22.0 million, $22.0 million, and $22.0 million, respectively.

NOTE 6. INVENTORY

As of March 31, 2025 and December 31, 2024, inventory consists of the following (in thousands):

	March 31, 2025	December 31, 2024
Raw materials	$ 37,912	$ 27,743
Work in process	12,088	8,765
Finished goods	15,545	15,012
Total inventory	$ 65,545	$ 51,520

NOTE 7. REVENUE

Net revenue for the periods presented represents sales of Amtagvi® and Proleukin® as follows (in thousands):

	Three Months Ended March 31,	
	2025	2024
Amtagvi®	$ 43,571	$ —
Proleukin®	5,753	715
Total net revenue	$ 49,324	$ 715

Revenue from Proleukin® was primarily related to sales made to specialty distributors and authorized treatment centers ("ATCs") in the U.S. market to support the commercialization of Amtagvi®. Amtagvi® revenue is recognized upon patient infusion, while Proleukin® revenue is recognized upon transfer of control, either upon shipment or upon delivery to customers, which include specialty distributors, clinical manufacturers, research organizations, and ATCs.

Revenue from product sales was recorded net of GTN adjustments. The following table summarizes GTN adjustments for the periods presented (in thousands):

	Three Months Ended March 31,	
	2025	2024
Gross revenue	$ 49,653	$ 719
GTN adjustments:		
Government rebates and chargebacks	(145)	—
Wholesaler fees and cash discounts	(169)	(4)
Other rebates, returns, discounts and adjustments	(15)	—
Total GTN adjustments	(329)	(4)
Net revenue	$ 49,324	$ 715

Consolidated net product revenue by geographic area for the periods presented is as follows (in thousands):

	Three Months Ended March 31,	
	2025	2024
United States	$ 48,520	$ —
Rest of world	804	715
Net revenue	$ 49,324	$ 715

Net product revenue in the U.S. is comprised of Amtagvi® revenue, as well as Proleukin® sales to support the ongoing commercialization of Amtagvi®. Net product revenue to date for the rest of world is comprised of sales of Proleukin® into markets outside of the U.S., primarily into European markets.

The following table summarizes the amount and percentage of gross revenue attributable to customers that represented more than 10% of the Company's gross revenue and all other customers as a group for the three months ended March 31, 2025 and 2024, respectively (in thousands, except percentages):

	Three Months Ended March 31, 2025		Three Months Ended March 31, 2024	
	$	%	$	%
Customer A	$ —	0%	$ —	0%
Other customers	49,653	100%	719	100%
Gross revenue	$ 49,653	100%	$ 719	100%
GTN adjustments	(329)		(4)	
Net revenue	$ 49,324		$ 715	

NOTE 8. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consists of the following (in thousands):

	March 31, 2025	December 31, 2024
Leasehold improvements	$ 67,375	$ 67,375
Lab, process, and validation equipment	25,423	25,477
Utility equipment	5,990	5,990
Office furniture and equipment	1,998	1,998
Computer software	8,512	8,512
Computer equipment	448	448
Machinery and equipment	363	363
Construction in progress	40,238	34,938
Total property and equipment, cost	$ 150,347	$ 145,101
Less: Accumulated depreciation and amortization	(38,763)	(36,020)
Property and equipment, net	$ 111,584	$ 109,081

Depreciation and amortization expense for the three months ended March 31, 2025 and 2024, was $2.8 million and $3.0 million, respectively.

NOTE 9. ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	March 31, 2025	December 31, 2024
Accrued payroll and employee related expenses	$ 26,369	$ 31,910
Clinical related	20,865	13,017
Manufacturing related	10,479	10,084
Facilities related	7,218	6,748
Legal and related services	2,900	2,466
Inventory and distribution related	10,726	12,471
Other accrued expenses	6,148	5,240
Total accrued expenses	$ 84,705	$ 81,936

NOTE 10. STOCKHOLDERS' EQUITY

Common Stock

The Company's certificate of incorporation, as amended, authorizes the issuance of up to 500,000,000 shares of the Company's common stock, par value $0.000041666. As of March 31, 2025, 333,934,387 shares of the Company's common stock were issued and outstanding.

Public Offerings

On February 22, 2024, the Company closed an underwritten public offering of 23,014,000 shares of its common stock at a public offering price of $9.15 per share, before underwriting discounts and commissions. The total net proceeds to the Company from the offering were $197.4 million after deducting underwriting discounts and commissions and offering expenses payable by the Company.

On July 13, 2023, the Company closed an underwritten public offering of 23,000,000 shares of the Company's common stock, which included 3,000,000 shares of common stock issued pursuant to the exercise of the option granted to the underwriters, at a public offering price of $7.50 per share, before underwriting discounts and commissions. The total net proceeds to the Company from the offering, including the exercise of the option by the underwriters, were $161.5 million after deducting underwriting discounts and commissions and offering expenses payable by the Company.

At the Market Offering Program

On November 18, 2022, the Company entered into an Open Market Sale Agreement (the "2022 Sale Agreement") with Jefferies LLC ("Jefferies"). Under the terms of the 2022 Sale Agreement, the Company was able to, from time to time, at its sole discretion, issue and sell through Jefferies, acting as a sales agent, up to $500.0 million of shares of the Company's common stock. On June 16, 2023, the Company entered into a new Open Market Sale Agreement (the "2023 Sale Agreement"), which superseded and replaced in its entirety the 2022 Sale Agreement, which was terminated by the Company. Under the terms of the 2023 Sale Agreement, the Company may, from time to time, in its sole discretion, issue and sell through Jefferies, acting as a sales agent, up to $450.0 million of shares of the Company's common stock. The issuance and sale, if any, of the shares of common stock by the Company under the 2023 Sale Agreement was or will be made pursuant to a prospectus supplement dated June 16, 2023 to the Company's Registration Statement on Form S-3ASR, which became effective immediately upon filing with the SEC on June 16, 2023.

Pursuant to the 2023 Sale Agreement, Jefferies may sell the Common Shares by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933, as amended. Jefferies will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the Common Shares from time to time, based upon instructions from the Company (including any price or size limits or other customary parameters or conditions the Company may impose). The Company will pay Jefferies a commission of up to 3.0% of the gross sales proceeds of any Common Shares sold through Jefferies under the 2023 Sale Agreement.

The Company is not obligated to make any sales of Common Shares under the 2023 Sale Agreement. The offering of Common Shares pursuant to the 2023 Sale Agreement will terminate upon the earlier to occur of (i) the issuance and sale, through Jefferies, of all Common Shares subject to the 2023 Sale Agreement and (ii) termination of the 2023 Sale Agreement in accordance with its terms.

During the three months ended March 31, 2025, the Company raised approximately $148.9 million in net proceeds, through the sale of 25,599,389 shares of common stock pursuant to the 2023 Sale Agreement at a weighted average price per share of $5.94. No sales were made pursuant to the 2023 Sales Agreement during the three months ended March 31, 2024.

Preferred Stock

The Company's certificate of incorporation authorizes the issuance of up to 50,000,000 shares of "blank check" preferred stock. As of March 31, 2025, 17,000 shares were designated as Series A Convertible Preferred Stock and 11,500,000 shares were designated as Series B Convertible Preferred Stock.

Series A Convertible Preferred Stock

A total of 17,000 shares of Series A Convertible Preferred Stock have been authorized for issuance under the Company's Certificate of Designation of Preferences and Rights of Series A Convertible Preferred Stock. The shares of Series A Convertible Preferred Stock have a stated value of $1,000 per share and are initially convertible into shares of common stock at a price of $2.00 per share, subject to adjustment. Each share of Series A Preferred Stock is initially convertible into 500 shares of common stock.

The Series A Convertible Preferred Stock may, at the option of each investor, be converted into fully paid and non-assessable shares of common stock. The holders of shares of Series A Convertible Preferred Stock do not have the right to vote on matters that come before the Company's stockholders. In the event of any dissolution or winding up of the Company, proceeds shall be paid pari passu among the holders of common stock and preferred stock, pro rata based on the number of shares held by each holder. The Company may not declare, pay, or set aside any dividends on shares of capital stock of the Company (other than dividends on shares of common stock payable in shares of common stock) unless the holders of the Series A Convertible Preferred Stock shall first receive an equal dividend on each outstanding share of Series A Convertible Preferred Stock.

During the three months ended March 31, 2025 and 2024, no shares of Series A Convertible Preferred Stock were converted into shares of common stock. As of March 31, 2025 and December 31, 2024, 194 shares of Series A Convertible Preferred Stock (that are convertible into 97,000 shares of common stock) remained outstanding.

Series B Convertible Preferred Stock

A total of 11,500,000 shares of Series B Convertible Preferred Stock are authorized for issuance under the Company's Series B Certificate of Designation of Rights, Preferences and Privileges of Series B Convertible Preferred Stock. The shares of Series B

Convertible Preferred Stock have a stated value of $4.75 per share and are convertible into shares of the Company's common stock at an initial conversion price of $4.75 per share. Each share of Series B Preferred Stock is initially convertible into 1 share of common stock.

The Series B Convertible Preferred Stock may, at the option of each investor, be converted into fully paid and non-assessable shares of common stock. The holders of Series B Convertible Preferred Stock do not have the right to vote on matters that come before the Company's stockholders. In the event of any dissolution or winding up of the Company, proceeds shall be paid pari passu among the holders of common stock and preferred stock, pro rata based on the number of shares held by each holder. Holders of Series B Convertible Preferred Stock are entitled to dividends on an as-if-converted basis in the same form as any dividends actually paid on shares of the Series A Convertible Preferred Stock or the Company's common stock. So long as any Series B Convertible Preferred Stock remains outstanding, the Company may not redeem, purchase, or otherwise acquire any material amount of the Series A Convertible Preferred Stock or any securities junior to the Series B Convertible Preferred Stock.

During the three months ended March 31, 2025, 909,491 shares of Series B Convertible Preferred Stock were converted into 909,491 shares of common stock. No shares of Series B Convertible Preferred Stock were converted into shares of common stock for the three months ended March 31, 2024. As of March 31, 2025 and December 31, 2024, 1,932,667 and 2,842,158 shares of Series B Preferred Stock (that are convertible into 1,932,667, and 2,842,158 shares of common stock) remained outstanding, respectively.

Equity Incentive Plans

The Company has multiple equity incentive plans under which it grants awards.

As of June 11, 2024, the Company's stockholders approved the termination of the 2014 Equity Incentive Plan (the "2014 Plan"). In addition, the Company's stockholders approved the recapture by the 2018 Equity Incentive Plan (the "2018 Plan") of awards granted under the 2014 Plan that expire, terminate, or are cancelled or forfeited without being settled, vested, or exercised after the stockholders' approval.

On April 22, 2018, the Company's Board of Directors (the "Board") adopted the Iovance Biotherapeutics, Inc. 2018 Equity Incentive Plan, (the "2018 Plan"), which was approved by the Company's stockholders in June 2018. The 2018 Plan as approved initially authorized the issuance up to an aggregate of 6,000,000 shares of the common stock in the form of incentive (qualified) stock options, non-qualified options, common stock, stock appreciation rights, restricted stock awards, restricted stock units, other stock-based awards, other cash-based awards or any combination of the foregoing. On June 8, 2020, the Company's stockholders approved an amendment to the 2018 Plan to increase the number of shares available for issuance upon the exercise of stock options under the 2018 Plan from 6,000,000 to 14,000,000 shares, which became effective immediately. Additionally on June 10, 2022, the Company's stockholders approved an amendment to the 2018 Plan to increase the number of shares available for issuance upon the exercise of stock options under the 2018 Plan from 14,000,000 to 20,700,000 shares, which became effective immediately. On June 6, 2023, the Company's stockholders approved an amendment to the 2018 Plan to increase the number of shares available for issuance under the 2018 Plan from 20,700,000 to 29,700,000 shares, which became effective immediately. On June 11, 2024, the Company's stockholders approved an amendment to the 2018 Plan to increase the number of shares available for issuance under the 2018 Plan from 29,700,000 to 36,700,000 shares and permit share recapture from the 2014 Plan, which became effective immediately. As of March 31, 2025, 3,207,191 shares of the Company's common stock were available for grant under the 2018 Plan, including shares recaptured from the 2014 Plan.

On September 22, 2021, the Board adopted the Iovance Biotherapeutics, Inc. 2021 Inducement Plan (the "2021 Inducement Plan"). The 2021 Inducement Plan provides for the grant of non-qualified options, common stock, stock appreciation rights, restricted stock awards, restricted stock units, other stock-based awards, other cash-based awards, or any combination of the foregoing. The 2021 Inducement Plan was recommended for approval by the Compensation Committee of the Board (the "Compensation Committee"), and subsequently approved and adopted by the Board without stockholder approval pursuant to Rule 5635(c)(4) of the rules and regulations of The Nasdaq Stock Market LLC (the "Nasdaq Listing Rules").

The Board initially reserved 1,000,000 shares of the Company's common stock for issuance pursuant to equity awards granted under the 2021 Inducement Plan, and the 2021 Inducement Plan is administered by the Compensation Committee. On January 12, 2022, the Compensation Committee approved an amendment to the 2021 Inducement Plan solely to increase the number of shares reserved for issuance under the 2021 Inducement Plan from 1,000,000 shares of the Company's common stock to 1,750,000 shares of the Company's common stock without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules.

The Compensation Committee approved additional amendments to the 2021 Inducement Plan solely to increase the number of shares reserved for issuance under the 2021 Inducement Plan from 1,750,000 to 2,250,000 shares of the Company's common stock on March 13, 2023 from 2,250,000 to 2,750,000 shares of the Company's common stock on February 26, 2024, and from 2,750,000 shares to 4,750,000 shares on November 22, 2024 without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, equity awards under the 2021 Inducement Plan may only be made to an employee if such employee is granted such equity awards in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. In addition, awards under the 2021 Inducement Plan may only be made to employees who have not previously been an employee or member of the Board (or any parent or subsidiary of the Company) or following a bona fide period of non-employment of the employee by the Company (or a parent or subsidiary of the Company). As of March 31, 2025, 816,381 shares of the Company's common stock were available for grant under the Inducement Plan.

Stock Options

A summary of the status of stock options as of March 31, 2025 and the changes during the three months ended March 31, 2025 are presented in the following table:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contract Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	18,218,126	$ 17.41		$
Issued	896,990	4.99		
Exercised	(2,586)	5.80		
Expired/Cancelled	(313,863)	17.08		
Outstanding at March 31, 2025	18,798,667	$ 16.83	6.14	$ —
Ending vested and expected to vest at March 31, 2025	18,798,667	$ 16.83	6.14	$ —
Options exercisable at March 31, 2025	14,636,506	$ 19.43	5.35	$ —

As of March 31, 2025, there was $19.5 million of total unrecognized compensation expense related to unvested employee stock options. The unrecognized compensation expense is estimated to be recognized over a period of 1.87 years as of March 31, 2025. The weighted average grant date fair value for employee options granted under the Company's stock option plans during the three months ended March 31, 2025 was $3.58 per option.

The aggregate intrinsic value in the table above reflects the total pre-tax intrinsic value (the difference between the Company's closing stock price on the last trading day of the quarter ended March 31, 2025 and the exercise price of the options, multiplied by the number of in-the-money stock options) that would have been received by the option holders had all option holders exercised their options on March 31, 2025. The intrinsic value of the Company's stock options changes based on the closing price of the Company's common stock.

Employee Stock Purchase Plan

In June 2020, the Company adopted the 2020 ESPP upon its approval by the Company's shareholders at its Annual Stockholders Meeting on June 8, 2020. The Company reserved 500,000 shares of its common stock for issuance under the 2020 ESPP. On June 6, 2023, the Company's stockholders approved an amendment to the 2020 ESPP to increase the number of shares reserved for issuance under the 2020 ESPP from 500,000 shares of the Company's common stock to 1,400,000 shares of the Company's common stock, which became effective immediately. On June 11, 2024, the Company's stockholders approved an amendment to the 2020 ESPP, to increase the number of shares reserved for issuance under the 2020 ESPP from 1,400,000 to 1,900,000 shares of the Company's common stock, which became effective immediately.

Under the 2020 ESPP, employees of the Company can purchase shares of its common stock based on a percentage of their compensation subject to certain limits. The purchase price per share is equal to the lower of 85% of the fair market value of its common stock on the offering date or the purchase date with a six-month look-back feature. The 2020 ESPP purchases are settled with common stock from the 2020 ESPP's previously authorized and available pool of shares.

The compensation expense related to the 2020 ESPP for the three months ended March 31, 2025 and 2024 was $0.4 million, and $0.4 million, respectively. As of March 31, 2025, there was $0.3 million of unrecognized compensation cost associated with the 2020 ESPP, which is expected to be recognized over the remaining 2.3 months.

Restricted Stock Units and Performance Restricted Stock Units

In addition to RSUs that have time-based vesting requirements, from time to time the Company may issue RSUs that include certain performance vesting criteria based upon the satisfaction of stated objectives ("PRSUs"). Compensation expense related to PRSUs is based on the grant date fair value of the award and recorded from the period that achievement is determined to be probable through the stated service period associated with the award.

A summary of the status of RSUs and PRSUs as of March 31, 2025 and the changes during the three months ended March 31, 2025 are presented in the following table:

	Number of RSUs and PRSUs	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2024	9,547,643	$ 15.08
Granted	6,514,120	4.10
Vested/Released	(3,558,628)	16.33
Canceled/Forfeited	(342,940)	11.09
Outstanding at March 31, 2025	12,160,195	$ 8.95
Ending vested and expected to vest at March 31, 2025	12,160,195	$ 8.95

As of March 31, 2025, there was $89.1 million of unrecognized stock-based compensation expense associated with unvested RSUs and PRSUs, which the Company expects to recognize over a remaining weighted-average period of 2.38 years. The aggregate intrinsic value of the unvested RSUs and PRSUs outstanding as of March 31, 2025 was $40.5 million.

Stock-Based Compensation

Total stock-based compensation expense related to the Company's stock-based awards was recorded on the condensed consolidated statements of operations, as follows (in thousands):

	Three Months Ended March 31,	
	2025	2024
Cost of sales	$ 2,420	$ —
Research and development	9,917	8,915
Selling, general, and administrative	10,578	8,263
Total stock-based compensation expense	$ 22,915	$ 17,178

The amount included in capitalized inventory for stock-based compensation expense for personnel engaged with manufacturing activities was $1.3 million as of March 31, 2025, and immaterial as of March 31, 2024.

Total stock-based compensation expense by type of award was as follows (in thousands):

	Three Months Ended March 31,	
	2025	2024
Stock option expense	$ 3,793	$ 5,763
Restricted stock expense	18,752	11,067
ESPP expense	370	348
Total stock-based compensation expense	$ 22,915	$ 17,178

NOTE 11. SEGMENT INFORMATION

The Company operates in one segment, focusing on innovating, developing, and commercializing therapies using its autologous TIL cell therapies for patients with solid tumor cancers. The Company is executing the U.S. launch of Amtagvi®, the first product within its autologous TIL cell therapy platform, while also marketing and distributing its Proleukin® product used in the Amtagvi® treatment regimen.

The Company's Chief Operating Decision Maker ("CODM") is the Chief Executive Officer, who uses net loss as measurement of segment loss and monitors results against budget to evaluate and assess performance of the Company and resource allocation within the Company. The measure of segment assets is reported on the balance sheet as total consolidated assets.

The table below highlights the Company's revenue, expenses and net loss for the segment and is reconciled to net loss on a consolidated basis for the three months ended March 31, 2025 and 2024.

	Three Months Ended March 31,	
(in thousands)	**2025**	**2024**
Net sales	$ 49,324	$ 715
Direct cost of goods sold (a)	$ 42,975	$ 2,330
Acquisition related cost of sales (b)	$ 5,440	$ 4,931
Royalties	$ 1,326	$ —
Total cost of sales	$ 49,741	$ 7,261
Expenses		
Research and development	$ 64,488	$ 70,288
General and administrative	$ 22,250	$ 17,962
Sales and marketing	$ 11,097	$ 5,154
Other segment items (c)	$ 17,911	$ 13,027
Total expenses	$ 115,746	$ 106,431
Net loss	$ (116,163)	$ (112,976)

a) Direct cost of goods sold represents inventory and period costs related to overhead and manufacturing costs of Amtagvi® as well as costs associated with the purchases and sales of Proleukin®. Also included are manufacturing and period costs incurred for Amtagvi® that do not meet specifications or a patient is unable to receive the infusion (i.e., scrap) unless they can be administered as part of a clinical trial in an expanded or early access program, or single-patient IND, in which cases related costs are recorded as research and development expenses based on the fact the Company receives clinical data related to these infusions. This category is provided to the CODM on a quarterly basis in comparison to that of previous quarters for review as these costs are controllable costs that indicate operating performance of the Company.

b) Acquisition related cost of sales represents amortization expenses for the developed technology intangible assets and the milestone payment recorded as part of the acquisition of Proleukin® and the fair value step-up of acquired Proleukin® inventory which is recognized as the acquired inventory units are sold. This category is provided to the CODM on a quarterly basis as costs in this category are often reviewed separately in evaluating the performance of the Company because these costs are fixed and uncontrollable costs in nature, and do not affect cashflows of the Company.

c) Other segment items include costs that are not considered significant expense segments nor reviewed by the CODM on a regular basis. Such amount includes stock-based compensation expenses, interest income, other income and expenses, and income tax benefits.

NOTE 12. LICENSES AND AGREEMENTS

National Institutes of Health (the "NIH") and the National Cancer Institute (the "NCI")

Cooperative Research and Development Agreement (the "CRADA")

In August 2011, the Company signed a five-year CRADA with the NCI to work on the development of adoptive cell immunotherapies in multiple solid tumor types, including unmodified TIL as a stand-alone therapy or in combination, improved methods for the generation and selection of TIL cell therapy with anti-tumor reactivity, and strategies for more potent TILs. The CRADA has been amended since then to, among other things, extend the term of the CRADA, include new indications such as bladder, lung, triple-negative breast, and Human Papilloma Virus ("HPV")-associated cancers, and modify the focus on the development of unmodified TIL as a stand-alone therapy or in combination, the evaluation in clinical trials of strategies for development of more potent TILs, such as selection of CD39/69 double negative cells and the use of certain inhibitors or other reagents in TIL expansion cultures.

In July 2024, the NCI and the Company entered into a fourth amendment to the CRADA to extend its term by an additional five years to August 2029. The fourth amendment also includes collaboration on preclinical and clinical development of enhanced tumor reactive TIL products for the treatment of a broad range of common epithelial cancers.

Pursuant to the terms of the CRADA, as amended, the Company was required to make quarterly payments of $0.5 million to the NCI for support of research activities through the end of 2024. Commencing in 2025, the Company is required to make quarterly payments of $0.9 million to the NCI for support of research activities through the end of the CRADA's term. To the extent the Company licenses patent rights relating to a TIL-based product candidate, the Company will be responsible for all patent-related expenses and fees, past and future, relating to the TIL-based product candidate. In addition, the Company may be required to supply certain test articles, including TIL, grown and processed under Current Good Manufacturing Practice ("cGMP") conditions, suitable for use in clinical trials. The Company or the NCI may unilaterally terminate the CRADA for any reason or for no reason at any time by providing written notice at least 60 days before the desired termination date. The Company recorded costs associated with the CRADA of $0.9 million and $0.5 million, for each of the three months ended March 31, 2025 and 2024, respectively, as research and development expenses.

Patent License Agreement Related to the Development and Manufacture of TIL Cell Therapies

The Company entered into an Exclusive Patent License Agreement (the "Patent License Agreement") with the NIH, an agency of the U.S. Public Health Service within the Department of Health and Human Services, in 2011, as amended in 2015. Pursuant to the Patent License Agreement, as amended, the NIH granted the Company licenses, including exclusive, co-exclusive, and non-exclusive licenses, to certain technologies relating to autologous tumor infiltrating lymphocyte adoptive cell therapy products for the treatment of metastatic melanoma, lung, breast, bladder, and HPV-positive cancers.

In May 2021, the Company entered into an Amended and Restated Patent License Agreement with NIH, which included the grant of additional exclusive, worldwide patent rights in the indications to interleukin-15 and interleukin-21 cytokine-tethered TIL technology, and expanded the non-exclusive, worldwide field of use to all cancers. In August 2022, the Company entered into a Second Amended and Restated Patent License Agreement with NIH to include additional exclusive, worldwide patent rights to TIL products expressing interleukin-12, expanded rights to TIL selection technologies previously licensed under the Exclusive Patent License Agreement below, and additional non-exclusive, worldwide patent rights to certain technologies related to enhancing TIL potency.

The Second Amended and Restated Patent License Agreement requires the Company to pay royalties based on a percentage of net sales in jurisdictions where patent rights exist, which percentage can fall into a tier that may be less than one percent to mid-single digits depending upon certain events, including the exclusivity of the rights, and the Company expects lower overall royalty payments as a result. The Company is also required to pay potential milestone payments on the achievement of certain clinical, regulatory, and commercial sales milestones for each of the indications and other direct costs incurred by the NIH pursuant to the Second Amended and Restated Patent License Agreement. The Company has made and anticipates making additional payments that could range from several hundred thousand dollars to the mid-single-digit millions of dollars in conjunction with certain development milestones, the approval of a BLA or its foreign equivalent, or the first U.S. and foreign commercial sales of any of its product candidates covered by the Second Amended and Restated Patent License Agreement. The term of the Second Amended and Restated Patent License Agreement continues until the expiry of the last-to-expire patent rights licensed thereunder, and the agreement contains standard termination provisions. The Company paid and recorded a $0.6 million milestone payment for an intellectual property license that was

payable within 60 days of successful completion of the first Company sponsored Phase 2 clinical study in melanoma, as research and development expenses, for the year ended December 31, 2023. The Company also paid a $1.5 million milestone payment for an intellectual property license that was payable within 60 days of the approval of Amtagvi® for use in the treatment of melanoma, and a $6.0 million milestone payment for an intellectual property license that was payable within 60 days of the approval of the first commercial sale of Amtagvi® for use in the treatment of melanoma in the U.S. in accordance with the requirements of the Second Amended and Restated Patent License Agreement. Both aforementioned milestone payments have been capitalized and recorded as intangible assets on the condensed consolidated balance sheet. During the three months ended March 31, 2025 and 2024, the Company recorded $0.2 million and a de minimis amount, respectively, as a component of cost of sales related to amortization of the milestone payments.

Exclusive Patent License Agreement Related to TIL Selection

On February 10, 2015, the Company entered into an exclusive patent license agreement (the "Exclusive Patent License Agreement") with the NIH under which the Company received an exclusive, worldwide license under the selected TIL patents. This license was superseded and replaced by the Second Amended and Restated Patent License Agreement.

H. Lee Moffitt Cancer Center

Research Collaboration and Clinical Grant Agreements with Moffitt

In June 2020, the Company entered into a Sponsored Research Agreement (the "SRA") with the H. Lee Moffitt Cancer Center ("Moffitt"), with a term that ended either upon completion of the research thereunder or on July 1, 2022, whichever is sooner. The SRA has been extended multiple times and currently has an expiration date of May 31, 2025. The Company recorded research development costs of $0.1 million for each of the three months ended March 31, 2025 and 2024.

The University of Texas M.D. Anderson Cancer Center

Strategic Alliance Agreement

In April 2017, the Company entered into a Strategic Alliance Agreement (the "SAA") with The University of Texas M.D. Anderson Cancer Center ("MDACC"), under which the Company and MDACC agreed to conduct clinical and preclinical research studies. The Company agreed in the SAA to provide total funding not to exceed approximately $14.2 million for the performance of the multi-year studies under the SAA, of which approximately $5.3 million has been funded to date and has been recorded as research and development expense. In return, the Company acquired all rights to inventions resulting from the studies and has been granted a non-exclusive, sub-licensable, royalty-free, and perpetual license to specified background intellectual property of MDACC reasonably necessary to exploit, including the commercialization thereof. The Company has also been granted certain rights in clinical data generated by MDACC outside of the clinical trials to be performed under the SAA. The SAA's term shall continue in effect until the later of the fourth anniversary of the SAA or the completion or termination of the research and receipt by the Company of all deliverables due from MDACC thereunder. On March 28, 2024, the Company and MDACC entered into the first amendment to the SAA, under which both parties agreed to conduct additional preclinical research studies. The Company recorded zero research and development costs for the three months ended March 31, 2025 and a benefit of $0.4 million for the three months ended March 31, 2024, as a result of finalization of the cost reconciliation.

WuXi Advanced Therapies, Inc.

In November 2016, the Company entered into a manufacturing services agreement (the "First Wuxi MSA") with WuXi Apptec, Inc. ("WuXi Apptec") pursuant to which WuXi Apptec agreed to provide manufacturing and other services for two cGMP manufacturing suites for clinical manufacturing and related testing services. The First WuXi MSA was amended and restated in December 2017, further amended and restated and assigned to the Company's subsidiary Iovance Biotherapeutics Manufacturing LLC ("Iovance Manufacturing LLC"), and Wuxi Advanced Therapies, Inc. in January 2020, and further amended in November 2020 and December 2021. The First WuXi MSA expired in November 2022.

In October 2022, Iovance Manufacturing LLC entered into an additional three-year manufacturing and services agreement (the "Second Wuxi MSA") with WuXi Advance Therapies, Inc. and its parent company, WuXi Apptec Co., Ltd (collectively, "WuXi"). Under the Second WuXi MSA, Iovance Manufacturing LLC entered into a statement of work for two cGMP manufacturing suites to be operated by WuXI for Iovance Manufacturing LLC to support clinical and commercial manufacturing and related testing services. The Second WuXi MSA and its related statement of work superseded the statements of work under the First WuXi MSA

with respect to manufacturing in the two suites and expire on December 31, 2025. Iovance Manufacturing LLC may unilaterally terminate the statement of work for clinical and commercial manufacturing with written notice of written notice of 6 months in year 3 of the term. The Company recorded costs associated with agreements with WuXi of $8.4 million and $5.5 million for the three months ended March 31, 2025 and 2024, respectively, as costs and expenses included in the condensed consolidated statement of operations or as inventory in the condensed consolidated balance sheets.

Cellectis S.A.

In December 2019, the Company entered into a research collaboration and exclusive worldwide license agreement whereby the Company will license gene-editing technology from Cellectis S.A. ("Cellectis"), a clinical-stage biopharmaceutical company, to develop TIL cell therapies that have been genetically edited, including a PD-1 inactivated product that the Company refers to as IOV-4001. Financial terms of the license include annual license payments and development, regulatory and sales milestone payments from the Company to Cellectis, as well as royalty payments based on net sales of TALEN®-modified TIL products. The Company recorded costs associated with the license agreement with Cellectis of $0.1 million for each of the three months ended March 31, 2025 and 2024, respectively, as research and development expense.

Novartis Pharma AG and Related Entities

In January 2020, the Company obtained a license from Novartis Pharma AG ("Novartis") to develop and commercialize an antibody cytokine engrafted protein, which the Company refers to as IOV-3001. Under the agreement, the Company paid an upfront payment to Novartis and may pay future milestones related to initiation of patient dosing in various phases of clinical development for IOV-3001 and approval of the product in the U.S., EU and Japan. Novartis is also entitled to low-to-mid single digit percentage royalties from commercial sales of the product. The Company recorded costs associated with the license agreement from Novartis of $10.0 million as research and development expenses for the year ended December 31, 2020. The Company recorded $2.5 million related to the initiation of patient dosing for the three months ended March 31, 2025. No expenses were recorded for the three months ended March 31, 2024.

On May 18, 2023, as part of the completion of the Acquisition, the Company inherited two historical asset purchase agreements, one historical master cell bank license and working cell bank transfer agreement and one historical license agreement from Clinigen with Novartis AG, Novartis Pharma AG and Novartis Vaccines and Diagnostics, Inc. pursuant to which, among other things, the Company may be required to make future milestone payments based on net sales (as defined in the relevant underlying agreements) in the U.S. and the rest of world, which includes any and all sales outside of the U.S. The maximum amount of these milestone payments payable under these agreements is $30.0 million upon reaching several certain net sales amounts in the U.S. and $15.0 million upon reaching several certain net sales amounts in the rest of the world, of which 25% of each milestone payment will be reimbursed by Clinigen by deduction from the deferred consideration due under the Option Agreement in the period such milestone payment is made. To date, the net sales milestones have not been achieved, and, therefore, no payments were made under these agreements for either the three months ended March 31, 2025 and 2024.

Boehringer Ingelheim Biopharmaceuticals GmbH

On May 18, 2023 as part of the completion of the Acquisition, the Company inherited a manufacturing and supply agreement from Clinigen with Boehringer Ingelheim Biopharmaceuticals GmbH ("BI") pursuant to which BI will carry out the processing, manufacturing and supply of Proleukin® in unlabeled vials. The term of this agreement is through October 2025, with automatic renewals for a period of two years unless terminated as permitted by the contract. Under this agreement, the Company must purchase a minimum number of vials each year at fixed prices determined by vial batch size. The total estimated purchase obligations under this agreement for the remainder of the year ending December 31, 2025, and the years ending December 31, 2026, and 2027 are $12.4 million, $8.8 million, and $7.9 million, respectively.

NOTE 13. LEASES

Operating Leases

The Company leases corporate office space in San Carlos, California, manufacturing, research and development lab facilities and office space in Philadelphia, Pennsylvania, including 136,000 square feet of commercial manufacturing and lab space at the *i*CTC, and research and development lab facilities in Tampa, Florida. The determination whether an arrangement is a lease occurs at inception, and for leases with terms greater than 12 months, the Company records a related right-of-use asset and lease liability at the present value of lease payments over the term. Many leases include fixed rental escalation clauses, renewal options and/or termination

options that are factored into the determination of lease payments when appropriate. The Company's leases do not provide an implicit rate, and thus the Company estimated the incremental borrowing rate in calculating the present value of the lease payments.

The Company's leases have remaining lease terms that range from less than one year to approximately 16 years. Some of the Company's leases include one or more options to renew with renewal terms that can extend the lease for additional years, or options to terminate the leases, both at the Company's discretion. The Company's leases may include options to extend or terminate the lease, which is considered in the lease term when it is reasonably certain that the Company will exercise any such options. Lease expense for minimum lease payments is recognized on a straight-line basis based on the fixed components of a lease arrangement.

Variable lease cost is determined based on performance or usage in accordance with the contractual agreements, and not based on an index or rate. Such costs that are not fixed in nature are recognized as incurred.

The Company also leases certain furniture and equipment that has a lease term of 12 months or less. Since the lease agreements do not include an option to purchase the underlying asset, the Company elected not to apply the recognition requirements of Topic 842 for short-term leases, however, the lease costs that pertain to the short-term leases are disclosed in the components of lease costs table below.

Relocation of the Headquarters Office Lease

On November 15, 2024, the Company entered into a sublease agreement (the "New Headquarters Lease") to relocate its office within the same building of its former San Carlos headquarters to lease approximately 16,731 square feet office space with the lease term of 24 months. The New Headquarters Lease commenced on December 15, 2024 and includes two options to extend the terms of the lease for 12 months each, exercisable under certain conditions and at a rate increase by 3% from the applicable monthly base rent of approximately $0.1 million. Upon the commencement date, the Company recognized operating lease liabilities and right-of-use assets of $2.3 million.

Simultaneously, the Company entered into an Agreement for Termination of Lease and Voluntary Surrender of Premises with its landlord related to its lease for its then existing and now former headquarters location to surrender 49,918 square feet office and laboratory space and paid an early lease termination payment to its landlord of $0.6 million and $2.5 million of related brokerage fees. In accordance with ASC 842, the termination of this lease resulted in derecognition of right-of-use assets and corresponding lease liabilities of $13.7 million and $22.3 million, respectively, which resulted in a $8.6 million gain, partially offset by the aforementioned lease termination related fees, recorded as interest and other income, net in the consolidated statement of operations for the year ended December 31, 2024.

In addition, as a result of the early termination of the former headquarters lease, the Company impaired approximately $7.4 million of long-lived assets, which included leasehold improvements, and furniture and fixtures, previously funded by the landlord through a tenant improvement allowance for the former corporate headquarters office lease (as discussed further below), and is included in the research and development expenses and selling, general and administrative expenses in the consolidated statement of operations for the year ended December 31, 2024.

Manufacturing Contracts

The Company uses contract manufacturing organizations (collectively, the "CMOs" and each a "CMO") to manufacture and supply TILs for clinical and commercial purposes. The CMO contractual obligations consist of the use of manufacturing facilities and minimum fixed commitment fees, such as personnel, general support fees, and minimum production or material fees. In addition to the minimum fixed commitment fees, the CMO contractual obligations include variable costs such as production and material costs in excess of the minimum quantity specified in each CMO agreement. During the term of each CMO agreement, the Company has access to and control of the use of a dedicated suite in each of the CMOs' facilities for manufacturing activities. The contracts with CMOs generally contain embedded operating leases based on the fact that the suites are used for the Company's production are implicitly identified, are used exclusively by the Company during the contractual term of the arrangements, and the CMOs have no substantive contractual rights to substitute the facilities used by the Company.

Further, the Company controls the use of the facilities by obtaining all of the economic benefits from the use of the facilities and directs the use of the facilities throughout the period of use. The terms of the CMO contracts include options to terminate the lease with advance notice of five to six months. The termination clauses and extension clauses are included in the calculation of the lease term for each of the CMOs when it is reasonably certain that it will not exercise such options.

For contracts with multiple deliverables, Topic 842 requires the Company to first identify a lease deliverable and non-lease deliverable included in the arrangements, and then allocate the fixed contractual consideration to the lease deliverable(s) and the non-lease deliverable(s) on a relative standalone selling price basis to determine the amount of operating lease right-of-use assets and liabilities. The Company identified the use of a dedicated suite as a single lease deliverable, and related labor services as a single non-lease deliverable in each of the CMO arrangements. Judgment is required to determine the relative standalone selling price of each deliverable as the observable standalone selling prices are not readily available. Therefore, management uses estimates and assumptions in determining relative standalone selling price of lease of a suite and labor service using information that includes market and other observable inputs to the extent possible.

The balance sheet classification of the Company's right-of-use asset and lease liabilities was as follows (in thousands):

	March 31, 2025	December 31, 2024
Operating lease right-of-use assets	$ 50,903	$ 55,201
Operating lease liabilities		
Current portion included in current liabilities	$ 8,499	$ 12,896
Long-term portion included in non-current liabilities	44,220	44,365
Total operating lease liabilities	$ 52,719	$ 57,261

The following table summarizes the components of lease expenses, which were included in total costs and expenses in the Company's condensed consolidated statements of operations and in inventory in the condensed consolidated balance sheets, and other information related to the Company's operating leases as follows (in thousands except weighted-average remaining lease terms and discount rates):

	Three Months Ended March 31,	
	2025	2024
Operating lease cost	$ 3,967	$ 3,797
Variable lease cost	942	1,608
Short-term lease cost	105	56
Total lease cost	$ 5,014	$ 5,461
Other information		
Cash paid for amounts included in the measurement of lease liabilities included in cash flows from operations	$ 4,210	$ 4,290
Increase(Decrease) in right-of-use assets from lease modifications	$ (1,429)	$ 11,297
Weighted-average remaining lease terms (years)	13.65	11.72
Weighted-average discount rates	7.8 %	7.8

As of March 31, 2025, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Year Ending December 31,	Facility leases	CMO embedded leases	Total
2025	$ 4,387	$ 6,433	$ 10,820
2026	5,490	—	5,490
2027	4,345	—	4,345
2028	4,432	—	4,432
2029	4,520	—	4,520
Thereafter	58,004	—	58,004
Total lease payments	$ 81,178	$ 6,433	$ 87,611
Less: Present value adjustment	(34,607)	(285)	(34,892)
Operating lease liabilities	$ 46,571	$ 6,148	$ 52,719

NOTE 14. LEGAL PROCEEDINGS

Shumacher Derivative Lawsuit. On December 11, 2020, a purported stockholder derivative complaint was filed by plaintiff Leo Shumacher against the Company, as nominal defendant, and then current directors, as defendants, in the Court of Chancery in the State of Delaware (the "Court of Chancery"). The complaint alleges breach of fiduciary duty and a claim for unjust enrichment in connection with alleged excessive compensation of certain non-executive directors of the Company and seeks unspecified damages on behalf of the Company. The parties agreed to a proposed settlement, which was submitted to the Court of Chancery on June 15, 2022. After a hearing on November 17, 2022, the Court of Chancery required the parties to take additional steps before it would approve the settlement. The Company, as nominal defendant, and its current directors, as defendants, answered the complaint on February 3, 2023. The parties agreed to a revised proposed settlement, which was submitted to the Court of Chancery on March 12, 2024. On July 17, 2024, the Court of Chancery declined to approve the settlement. The case will proceed to discovery. On January 17, 2025, a non-party stockholder (The Paul Berger Revocable Trust), which objected to the revised proposed settlement, filed a derivative complaint and letter with the Court suggesting consolidation. The Company intends to vigorously defend against these complaints.

Ohio Laborers Derivative Lawsuit. On September 11, 2024, a purported stockholder derivative complaint was filed by plaintiff Northern California Pipe Trades Trust Fund against the Company, as nominal defendant, and certain directors, as defendants, in the Court of Chancery. The complaint alleges breach of fiduciary duty in connection with the February 2024 underwritten public offering of 23,014,000 shares of the Company's common stock. On November 22, 2024, the defendants filed a motion to dismiss the complaint. On December 5, 2024, the plaintiff filed an amended complaint adding an additional director defendant. On January 10, 2025, defendants filed a motion to dismiss the amended complaint. On February 3, 2025, the Court approved substitution of Laborers' District Council and Contractors' Pension Fund of Ohio ("Ohio Laborers") as representative plaintiff. The Company intends to vigorously defend against this complaint.

Solomon Capital, LLC. On April 8, 2016, a lawsuit (the "First Solomon Suit") titled *Solomon Capital, LLC, Solomon Capital 401(K) Trust, Solomon Sharbat and Shelhav Raff v. Lion Biotechnologies, Inc.* was filed by Solomon Capital, LLC, Solomon Capital 401(k) Trust, Solomon Sharbat and Shelhav Raff ("Solomon Plaintiffs") against the Company in the Supreme Court of the State of New York, County of New York (index no. 651881/2016) (the "court"). The Solomon Plaintiffs allege that, between June and November 2012, they provided the Company $0.1 million and that they advanced and paid on behalf of the Company an additional $0.2 million.

The complaint further alleges that the Company agreed to (i) provide them with promissory notes totaling $0.2 million, plus interest, (ii) issue a total of 1,110 shares to the Solomon Plaintiffs (after the 1-for-100 reverse split of the Company's common stock effected in March 2013) (the "Equity Claim"), and (iii) allow the Solomon Plaintiffs to convert the foregoing funds into its securities in the next financing of the Company on the same terms offered to other investors, which Solomon Plaintiffs allege, should have given them the right to convert their advances and payments into shares of the Company's common stock in the restructuring that took effect in May 2013. Based on the foregoing, the Solomon Plaintiffs allege causes for breach of contract and unjust enrichment and demand judgment against the Company in an unspecified amount exceeding $1.5 million, plus interest. On June 3, 2016, the Company filed an answer and counterclaims in the lawsuits. The Company has asserted counterclaims for fraudulent inducement, fraudulent misrepresentation, fraudulent concealment, breach of fiduciary duty, and breach of contract, alleging principally that the counterclaim defendants misrepresented their qualifications and failed to disclose that Solomon Sharbat was the subject of an investigation by the Financial Industry Regulatory Authority ("FINRA") that resulted in the loss of his FINRA license.

In its counterclaims, the Company is seeking damages in an amount exceeding $0.5 million and an order rescinding any and all agreements that the Solomon Plaintiffs contend entitled them to obtain shares of Company stock. On May 12, 2020, the court granted the Company's motion for summary judgment limiting the Solomon Plaintiffs' damages for the Equity Claim to $47,420. The Solomon Plaintiffs filed a notice of appeal of this summary judgment on June 9, 2020. On July 2, 2020, the court granted the Company's motion to dismiss the First Solomon Suit for want of prosecution. On January 4, 2021, the court granted the Solomon Plaintiffs motion for reconsideration and reinstituted the case. On January 15, 2021, the Company filed a notice of appeal of the court's grant of the Solomon Plaintiffs motion for reconsideration. On May 11, 2021, the Appellate Division upheld the court's grant of the Solomon Plaintiffs' motion for reconsideration of the dismissal of the First Solomon Suit for want of prosecution. On January 22, 2025, Solomon Sharbat and Shelhav Raff (through new legal counsel) filed a motion for leave to file an amended complaint in the First Solomon Suit, which the Company opposed. On March 10, 2025, the Company filed a motion for summary judgment.

On September 27, 2019, the Solomon Plaintiffs filed a new lawsuit (through new legal counsel) (the "Second Solomon Suit") titled Solomon Capital, LLC, Solomon Capital 401(K) Trust, Solomon Sharbat and Shelhav Raff v. Iovance Biotherapeutics, Inc., f/k/a/ Lion Biotechnologies Inc. f/k/a/ Genesis Biopharma Inc., and Manish Singh in the Supreme Court of the State of New York,

County of New York (index no. 655668/2019). In the Second Solomon Suit, the Solomon Plaintiffs allege that they are third party beneficiaries of a "finder's fee agreement" that prior management entered into with a third party unlicensed entity in 2012 in connection with seeking financing, that an agreement or understanding existed between the Company and the plaintiffs that the plaintiffs would be paid fees and commissions (in cash and stock) if they obtained financing for the Company, and that they directly and indirectly introduced investors to the Company who invested in the Company, or were willing to invest in the Company. Finally, the Solomon Plaintiffs allege that they were promised a license to use the Company's technology in Israel. The plaintiffs claim that the Company breached the foregoing understandings, promises and agreements and, as a result, they are entitled to certain damages. The Solomon Plaintiffs also allege that Manish Singh, the Company's former Chief Executive Officer, committed fraud and took shares belonging to them. On February 18, 2020, the Company filed a removal petition and removed the Second Solomon Suit to the U.S. District Court for the Southern District of New York (the "District Court"), where the case has been assigned case no. 1:20-cv-1391. On May 22, 2020, the Company moved to dismiss the Second Solomon Suit for lack of personal jurisdiction. On March 26, 2021, the District Court denied the Company's motion to dismiss for lack of personal jurisdiction. The Company filed a response to the complaint in the Second Solomon Suit on April 30, 2021. On May 26, 2021, the Company and Singh filed motions for judgment on the pleadings with respect to the second and third claims asserted against the Company and all claims asserted against Singh, respectively, in the Second Solomon Suit. On January 5, 2022, the District Court granted the Company's motions for judgment on the pleadings, dismissing the second and third claims against the Company and dismissing all claims against Singh. On January 4, 2023, the District Court granted in part the Company's motion for sanctions against the Solomon Plaintiffs for violating Rule 11 of the Federal Rules of Civil Procedure, in a decision and order that dismissed the Solomon Plaintiffs' first claim against the Company, denied the Solomon Plaintiffs' motion for leave to amend the complaint, and ordered the Solomon Plaintiffs to pay the Company's attorneys' fees incurred in connection with the Rule 11 motion. Following the District Court's decision and order on the Rule 11 motion, only the Solomon Plaintiffs' fifth and sixth claims, for unjust enrichment and indemnification, respectively, remained pending against the Company. On October 26, 2023, the District Court granted the Company's motion for summary judgment and dismissed the Solomon Plaintiffs' fifth and sixth claims. On October 27, 2023, the District Court entered judgment for the Company and closed the Second Solomon Suit. On November 10, 2023, the Company filed a motion for attorneys' fees as the prevailing party in the action. On December 1, 2023, the Solomon Plaintiffs filed a notice of appeal to the U.S. Court of Appeals for the Second Circuit (the "Second Circuit Court"), appealing the District Court's orders (a) granting the motions for judgment on the pleadings filed on behalf of Singh and the Company, (b) granting the Company's Rule 11 motion, (c) denying the Solomon Plaintiffs' motions to compel discovery and re-open discovery, and (d) granting the Company's summary judgment motion. On December 22, 2023, the Company filed a motion for an order requiring the Solomon Plaintiffs to post an appeal bond, to ensure payment of the Company's appellate fees and costs should the Company prevail on the appeal. On May 9, 2024, the District Court issued an order granting the Company's motions for attorneys' fees and for an appeal bond. On June 28, 2024, the Company filed motions to dismiss the appeal on the grounds that the Solomon Plaintiffs (a) do not have an opening brief on file, which the Second Circuit Court denied, and (b) have not filed an appeal bond. The District Court entered judgment in favor of the Company on September 23, 2024, including a monetary award pursuant to the District Court's Rule 11 order and orders for attorneys' fees and costs. On October 9, 2024, the Second Circuit Court stated that it will dismiss the appeal unless the Solomon Plaintiffs post the appeal bond by October 23, 2024. The Solomon Plaintiffs then moved for an extension of time until November 23, 2024 to post the appeal bond. The Company filed an opposition to the motion. The Second Circuit Court denied the Solomon Plaintiffs' motion for an extension of time on November 7, 2024, and dismissed the appeal on November 8, 2024.

The Company intends to vigorously defend these complaints and pursue its counterclaims, as applicable. At the current stage of the litigation, in both the First Solomon Suit and the Second Solomon Suit, it is not possible to estimate the amount or range of possible loss that might result from an adverse judgment or a settlement of these matters.

The Company has been and may continue to be involved, from time to time, in legal proceedings and claims arising in the ordinary course of its business. Such matters are subject to many uncertainties and outcomes are not predictable with assurance. The Company accrues amounts, to the extent they can be reasonably estimated, that it believes are adequate to address any liabilities related to legal proceedings and other loss contingencies that it believes will result in a probable loss. While there can be no assurances as to the ultimate outcome of any legal proceeding or other loss contingency involving the Company, management does not believe any pending matter will be resolved in a manner that would have a material adverse effect on its financial position, results of operations or cash flows.

NOTE 15. INCOME TAXES

The Company recorded a tax benefit of $1.8 million and $1.4 million for the three months ended March 31, 2025, and 2024, respectively, which resulted in effective tax rates of 1.6%, and 1.2%, respectively. The effective tax rate is different from the U.S.

statutory rate of 21% due to the full valuation allowance against tax losses in the U.S. The income tax benefit for the periods presented primarily relates to operations in the UK and realization of related deferred taxes.

As of March 31, 2025, the Company continued to maintain its full valuation allowance against U.S. federal and state net deferred tax assets as it expected to be in a cumulative loss position and does not have sufficient positive evidence to support the realizability of its U.S. net deferred tax assets.

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

The following discussion and analysis of our results of operations and financial condition should be read in conjunction with our financial statements and the notes to those financial statements that are included elsewhere in this report. Our discussion includes forward-looking statements based upon current expectations that involve risks and uncertainties, such as our plans, objectives, expectations and intentions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of a number of factors, including those set forth under the "Business" section and elsewhere in this report. We use words such as "may," "will," "might," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "aim," "potential," "continue," "ongoing," "goal," "forecast," "guidance," "outlook," or the negative of these terms or other similar expressions to identify forward-looking statements, although not all forward-looking statements contain these words. All forward-looking statements included in this report are based on information available to us on the date hereof and, except as required by law, we assume no obligation to update any such forward-looking statements.

Overview

We are a commercial-stage biopharmaceutical company pioneering a transformational approach to treating cancer by harnessing the human immune system's ability to recognize and destroy diverse cancer cells using therapies personalized for each patient. Our mission is to be the global leader in innovating, developing and delivering tumor infiltrating lymphocyte, or TIL, cell therapies for patients with solid tumor cancers. We are executing the U.S. launch of Amtagvi® (lifileucel), the first product within our autologous TIL cell therapy platform, while also marketing Proleukin® (aldesleukin), an interleukin-2, or IL-2, product used in the Amtagvi® treatment regimen and in other applications. Amtagvi® is the first and the only one-time, individualized T cell therapy to receive U.S. Food and Drug Administration, or the FDA, approval for a solid tumor cancer. Amtagvi® is a tumor-derived autologous T cell immunotherapy indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. This indication was approved in February 2024 under accelerated approval based on an endpoint of overall response rate, or ORR. Continued approval for this indication may be contingent upon verification and description of clinical benefit in future confirmatory trials. Amtagvi® and Proleukin® are part of a treatment regimen that also includes lymphodepletion.

Beyond the U.S., we plan to launch Amtagvi® into additional markets with a high prevalence of advanced melanoma, including the European Union, or EU, United Kingdom, or UK, Canada, Switzerland, and Australia. In June 2024, we submitted a centralized marketing authorization application, or MAA, to the European Medicines Agency, or the EMA, for lifileucel. In August 2024, the MAA was validated and accepted for review by the EMA. In October 2024, an MAA was submitted to the Medicines and Healthcare products Regulatory Agency in the UK. A new drug submission, or NDS, was deemed eligible for Notice of Compliance with Conditions or NOC/c by Health Canada and submitted in December 2024 and then accepted in January 2025. The NOC/c policy includes a prioritized 200-day review process for potential NDS approval in mid-2025. If approved, lifileucel is expected to be the first and only approved therapy in this treatment setting in these markets. Across the U.S. and other targeted global markets, Amtagvi® has the potential to address more than 20,000 previously treated advanced melanoma patients annually.

Iovance was founded to build upon the promise of TIL cell therapy that was previously demonstrated in single-center clinical trials at academic research centers, including the National Cancer Institute, or the NCI. Our multi-center trials, novel TIL cell therapy products, manufacturing processes, facilities, and bioanalytical platforms have transformed TIL cell therapy into a commercially viable treatment which thousands of patients with cancer can access.

We manufacture Amtagvi® and our investigational TIL cell therapies using centralized, scalable, and proprietary manufacturing processes which rejuvenate and multiply polyclonal T cells unique to each patient into the billions and yields a cryopreserved, individualized therapy. Amtagvi® is manufactured for commercial use at our manufacturing facility, the Iovance Cell Therapy Center, or the *i*CTC, and by a contract manufacturing organization, or CMO.

Our development pipeline includes multicenter trials of TIL cell therapies in additional treatment settings and indications for solid tumor cancers. To potentially improve outcomes for patients, we are investigating TIL monotherapies for patients previously treated with standard of care therapies and TIL cell therapy in combination with standard of care therapies for patients in earlier treatment settings. We are conducting two ongoing registrational trials to support a supplementary BLA, or sBLA, of lifileucel in frontline advanced melanoma and in advanced non-small cell lung cancer, or NSCLC, following standard of care chemo-immunotherapy. We are also developing next generation therapies, such as genetically modified TIL cell therapy and next generation cytokines.

Corporate Strategy

A global leader in innovating, developing, and delivering TIL cell therapy

Our mission is to be the global leader in innovating, developing, and delivering TIL cell therapy for patients with solid tumor cancers. We are pioneering this transformational approach to cure cancer by harnessing the human immune system's ability to recognize and destroy diverse cancer cells in each patient. As we continue to execute the U.S. launch of Amtagvi® and advance our pipeline, we are committed to continuous innovation to develop TIL cell therapies and optimize TIL treatment regimens that may extend and improve life for patients with cancer.

Successfully commercialize our lead product Amtagvi® for the treatment of post-anti-PD-1 advanced melanoma in the U.S.

Following U.S. FDA approval of Amtagvi® for the treatment of patients with post-anti-PD-1 advanced melanoma on February 16, 2024, our top priority is continuing to leverage our experienced marketing, payer access, and distribution teams, as well as a sales force with extensive experience in oncology and cell therapy for our commercialization efforts. Our medical affairs team is also educating key opinion leaders, or KOLs, about Amtagvi® and TIL cell therapy, as well as presenting and publishing our clinical results.

We are focusing ongoing Amtagvi® commercialization efforts on four primary areas:

- supporting operations and patient enrollment at authorized treatment centers, or ATCs, in the U.S. and activating ATCs in the EU, UK, and Canada to prepare for anticipated 2025 regulatory approvals in those markets;
- educating, training, and collaborating with healthcare professionals, or HCPs, who will be administering our product, as well as community oncologists who will be referring patients to our ATCs and larger community practices that may become ATCs;
- operational excellence in launch execution, commercial manufacturing, and delivery of therapy; and
- continuous communication with payors about the value of Amtagvi® to facilitate strong reimbursement and patient access.

U.S. Commercial Launch of the First TIL Cell Therapy in Advanced Melanoma

Amtagvi®

Amtagvi® (lifileucel) was approved by the FDA on February 16, 2024, for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. The approval is based on safety and efficacy results from the C-144-01 clinical trial, a global, multicenter trial investigating Amtagvi® in patients with advanced melanoma previously treated with anti-PD-1 therapy and targeted therapy, where applicable.

Amtagvi® is manufactured using a proprietary process to collect and multiply a patient's unique T cells from a portion of their tumor. Amtagvi® returns billions of the patient's T cells back to the body to fight cancer. Amtagvi® is administered to patients as part of a treatment regimen that includes lymphodepletion and a short course of high-dose Proleukin® (aldesleukin).

There are three key steps in the Amtagvi® treatment process.

- **Step 1: Sample Collection.** A tumor tissue sample of at least 1.5 cm in diameter is collected during a surgical resection and shipped to an approved, centralized manufacturing facility.

- **Step 2: Manufacturing.** Upon arrival at the manufacturing facility, TIL are separated from other cells within the patient's tumor tissue sample. Over the next 22 days, the cells are multiplied into the billions. Upon completion of manufacturing, Amtagvi® is quality tested to meet specific product release criteria. The final product is cryopreserved and sent back to the ATC for administration to the patient. Additional details on the Gen 2 manufacturing process are provided in the Manufacturing Process section of our Annual Report on Form 10-K.

- **Step 3: Treatment Regimen.** The Amtagvi® treatment regimen begins with non-myeloablative lymphodepletion, or NMA-LD, to suppress the immunosuppressive tumor microenvironment, which we believe enhances the efficacy of TIL cell therapy. After NMA-LD, Amtagvi® is infused and followed by a short course of up to six doses of Proleukin® to promote T cell activity.

Prior to the FDA approval of Amtagvi®, there were no FDA approved therapies for patients with advanced melanoma following anti-PD-1 therapy.

Proleukin®

Proleukin® (aldesleukin) is an IL-2 product used in the Amtagvi® treatment regimen and manufacturing process, as well as other commercial, clinical, manufacturing, and research settings, which provides additional revenue. In May 2023, we acquired the worldwide rights to Proleukin® as well as the manufacturing, supply, and commercialization income generated from such rights and associated operations from Clinigen Holdings Limited, Clinigen Healthcare Limited, and Clinigen, Inc, which we refer to collectively as Clinigen. Ownership of Proleukin® provides an additional revenue source, secures our Proleukin® supply chain, lowers cost of goods, and reduces clinical trial expenses for Proleukin® used with our TIL cell therapies.

Proleukin® has received regulatory approvals for treatment of adults with metastatic melanoma and metastatic renal cell carcinoma in the U.S. Proleukin® is also licensed in multiple countries around the world for treatment of patients with metastatic renal cell carcinoma and/or metastatic melanoma. We also sell aldesleukin for clinical trial use and for use in the manufacturing of various cell and gene therapies to numerous third-party clients.

Manufacturing capacity for forecasted commercial and clinical demand

We are the first company to obtain FDA approval for a TIL cell therapy product. We believe that we are the only company in the U.S. to have a centralized, scalable, and commercially viable TIL manufacturing process. In clinical trials, more than 700 patients have been treated with Iovance TIL cell therapy products manufactured using our proprietary processes across multiple indications. Iovance TIL cell therapies are manufactured for commercial use and clinical trials at our manufacturing facility, the *i*CTC, and by a CMO. The FDA authorized *i*CTC for commercial manufacturing of Amtagvi® as well as our CMO for additional capacity to supplement our internal manufacturing. As built, the two facilities together have capacity to treat several thousands of cancer patients annually with commercial product and clinical supply.

The *i*CTC is the first centralized and scalable current Good Manufacturing Practice, or cGMP, manufacturing facility dedicated to producing TIL cell therapies, as well as the first FDA-approved facility for commercial TIL cell therapy. Located in Philadelphia, Pennsylvania, the 136,000 square foot *i*CTC is among the largest cell therapy manufacturing facilities globally. *i*CTC expansion is underway which is expected to increase capacity to supply over five thousand patients annually. Our long-term goal is to establish a manufacturing network that can supply TIL cell therapies to over ten thousand patients per year. The proximity of the *i*CTC to multiple airports facilitates delivery of TIL cell therapies to treatment centers. The *i*CTC is expected to cover logistics and delivery of TIL cell therapies in North America, Europe, and Australia. Ownership of our manufacturing facility allows us to control internal manufacturing capacity and product quality, manage supply and delivery logistics, implement process improvement and realize potential cost efficiencies for TIL cell therapies that we may develop and commercialize. We are also exploring next generation TIL cell therapy manufacturing processes, treatments and technologies that may further streamline development timelines and costs. The *i*CTC has a flexible design that facilitates our expansion within the existing shell space and an option to build on an adjacent lot to support future growth and capacity needs.

We plan to carefully manage our cost structure and reduce the long-term cost of manufacturing our products. Details of related agreements are provided in Note 12. Licenses and Agreements section of this Quarterly Report on Form 10-Q.

TIL Cell Therapy Clinical Development in Advanced, Metastatic or Unresectable Solid Tumor Cancers

Our TIL cell therapy platform and manufacturing process have been initially validated through the FDA approval of Amtagvi®. TIL cell therapy is a T cell-based immunotherapy technology platform that leverages patient-specific cells to recognize and attack diverse cancer cells that are unique to each patient. Unlike other cell therapies that act on a single or small number of shared antigen targets common to certain tumors, our individualized T cell therapies are polyclonal or designed to target a variety of neoantigens that are unique to the patient or tumor. We believe this polyclonal cell therapy may be applicable to many solid tumor cancers, where the majority of immune targets are patient-specific.

We have investigated TIL cell therapy in global, multicenter clinical trials in advanced melanoma, cervical cancer, non-small cell lung cancer, or NSCLC, and head and neck squamous cell carcinoma, or HNSCC. Through ongoing academic collaborations, as well as government and other partners, we are investigating the next frontier for TIL cell therapy in other tumor types and treatment settings.

- **Frontline Advanced Melanoma:** In frontline advanced melanoma patients who are naïve to anti-PD-1 therapy, we are investigating lifileucel in combination with pembrolizumab in TILVANCE-301, a randomized Phase 3 clinical trial intended to support registration in advanced frontline melanoma as well as to serve as a confirmatory trial to support full approval in post-anti-PD-1 advanced melanoma. TILVANCE-301 is expected to enroll approximately 670 patients and features dual primary endpoints of ORR and progression free survival, or PFS, assessed by blinded independent review committee. We also added Cohort 1D to our IOV-COM-202 trial to investigate lifileucel in combination with relatlimab and nivolumab in frontline advanced melanoma patients.

- **Advanced Non-Small Cell Lung Cancer:** In NSCLC, we are investigating lifileucel TIL cell therapy in two clinical trials in NSCLC patient populations with significant unmet need. IOV-LUN-202 is a registrational clinical trial of lifileucel in advanced NSCLC patients who have progressed following chemotherapy and anti-PD-1 therapy. The IOV-COM-202 trial in solid tumors includes cohorts of NSCLC patients treated with lifileucel monotherapy and combination therapy. We added Cohorts 3D and 3E to our IOV-COM-202 trial to investigate lifileucel in combination with pembrolizumab and chemotherapy in frontline advanced NSCLC patients.

- **Advanced Endometrial Cancer:** We initiated a clinical trial, IOV-END-201, in the second quarter of 2024 for lifileucel in endometrial cancer to potentially address the unmet need for patients previously treated with platinum-based chemotherapy and anti-PD-1 therapy regardless of mismatch repair.

- **Next Generation TIL Cell Therapy:** Our first genetically modified, TIL cell therapy, IOV-4001, is being investigated in the multi-center Phase 2 efficacy portion of a first-in-human clinical trial, IOV-GM1-201, in previously treated patients with advanced melanoma or NSCLC. IOV-4001 utilizes the gene-editing TALEN® technology, licensed from the clinical-stage biotechnology company, Cellectis S.A., or Cellectis, to inactivate the gene coding for PD-1. A second next generation TIL cell therapy, IOV-5001, is in Investigational New Drug, or IND, enabling studies. IOV-5001 is a genetically engineered, inducible, and tethered interleukin-12 TIL cell therapy designed to enhance TIL efficacy while optimizing safety.

- **Next Generation IL-2:** A Phase 1/2 clinical trial is underway to investigate IOV-3001, a second-generation, modified interleukin-2 analog, for use in the TIL therapy treatment regimen. Preclinical studies of IOV-3001 demonstrated the potential for improved safety with strong effector T cell expansion.

- **Additional Solid Tumor Cancers:** Iovance TIL cell therapy has been investigated in additional solid tumor cancers in Iovance- and investigator-sponsored clinical trials. Lifileucel was evaluated as a monotherapy and in combination with pembrolizumab in the Phase 2 C-145-03 and IOV-COM-202 clinical trials in multiple patient cohorts with metastatic HNSCC, and in patients with advanced cervical cancer in the C-145-04 multicenter Phase 2 clinical trial. Indications studied in investigator sponsored clinical trials supported by Iovance include soft tissue sarcoma, osteosarcoma, pancreatic and colorectal cancer, platinum resistant ovarian cancer, anaplastic thyroid cancer, and triple negative breast cancer.

Next-Generation TIL Therapy Product Candidates

Our next-generation technology platforms are designed to optimize outcomes with TIL cell therapy across three key initiatives: genetic modifications, potency, and new treatment regimens.

- *Genetic modifications:* In addition to IOV-4001, we are pursuing several targets for genetic modification that utilize the gene-editing TALEN® platform licensed from Cellectis. Single- and multiple- knockouts may further harness the immune system response to cancer and potentially increase the potency of TIL cell therapy. Preclinical development is ongoing with additional TIL products and TIL-cell lines using transient and stable gene inactivation, which may expand and activate TIL to achieve better efficacy while avoiding systemic side effects.

- *Cytokine-Tethered TIL Therapy*: Our genetically engineered, inducible, and tethered IL-12 TIL cell therapy, designated IOV-5001, is in IND-enabling studies. In preclinical studies, IOV-5001 augmented anti-tumor activity in vitro, and a clinical trial of a prior generation IL-12 TIL therapy at the NCI showed improved efficacy. A pre-IND meeting was held with the FDA in the first quarter of 2025 to discuss IOV-5001, and an IND application submission is currently planned for the fourth quarter of 2025.

- *New treatment regimens:* We are exploring potential improvements to the TIL treatment regimen. We are investigating IOV-3001, a second generation, modified IL-2 analog, which we licensed from Novartis Pharma AG in 2020. We submitted an IND application for a phase 1/2 clinical trial of IOV-3001 for use in the TIL therapy treatment regimen in the third quarter of 2024, which was accepted in the fourth quarter of 2024. Results from non-human primate and IND-enabling studies of IOV-3001 were presented at the American Society of Clinical Oncology's 2024 Annual Meeting and demonstrate the potential for improved safety with strong effector T cell expansion.

Intellectual Property

We have established a leading intellectual property portfolio developed internally and licensed from third parties. We currently own more than 75 U.S. patents related to TIL cell therapy, including patents directed to compositions and methods of treatment in a broad range of cancers, such as U.S. Patent Nos. 10,130,659; 10,166,257; 10,272,113; 10,363,273; 10,398,734; 10,420,799; 10,463,697; 10,517,894; 10,537,595; 10,639,330; 10,646,517; 10,653,723; 10,695,372; 10,894,063; 10,905,718; 10,918,666; 10,925,900; 10,933,094; 10,946,044; 10,946,045; 10,953,046; 10,953,047; 11,007,225; 11,007,226; 11,013,770; 11,026,974; 11,040,070; 11,052,115; 11,052,116; 11,058,728; 11,083,752; 11,123,371; 11,141,438; 11,168,303; 11,168,304; 11,179,419; 11,202,803; 11,202,804; 11,220,670; 11,241,456; 11,254,913; 11,266,694; 11,273,180; 11,273,181; 11,291,687; 11,304,979; 11,304,980; 11,311,578; 11,337,998; 11,344,579; 11,344,580; 11,344,581; 11,351,197; 11,351,198; 11,351,199; 11,364,266; 11,369,637; 11,384,337; 11,433,097; 11,517,592; 11,529,372; 11,541,077; 11,713,446; 11,819,517; 11,857,573; 11,865,140; 11,866,688; 11,939,596; 11,969,444; 11,975,028; 11,981,921; 12,023,355; 12,024,718; 12,031,157; 12,104,172; 12,121,541; 12,159,700; 12,170,134; 12,188,048; 12,194,061; and 12,226,434. More than 40 of these patents are related to our Gen 2 TIL manufacturing processes and have terms that we anticipate will extend to October 2037 or January 2038, not including any patent term extensions or adjustments that may be available. Our owned and licensed intellectual property portfolio also includes patents and patent applications relating to TIL, marrow-infiltrating lymphocytes, or MIL, and peripheral blood lymphocyte, or PBL, therapies; frozen tumor-based TIL technologies; remnant TIL and digest TIL compositions, methods, and processes; methods of manufacturing TIL, MIL, and PBL therapies; the use of costimulatory and T cell modulating molecules in TIL cell therapy and manufacturing; stable and transient genetically-modified TIL cell therapies, including genetic knockouts of immune checkpoints; cytokine-tethered TIL cell therapies; methods of using immune checkpoint inhibitor, or ICIs, in combination with TIL cell therapies; TIL selection technologies; and methods of treating patient subpopulations.

Components of Operating Results

Revenues

Revenues for the three months ended March 31, 2025 represent product sales of Amtagvi®, as well as Proleukin®, primarily driven from sales in the U.S. to support the ongoing commercial launch of Amtagvi®, which received FDA approval in February 2024. Proleukin®, which we acquired the worldwide rights to in May 2023, is also sold in markets outside the U.S., primarily in the EU and UK. Prior to May 2023, we had not recognized any revenue.

Amtagvi® revenue is recognized upon patient infusion, while Proleukin® revenue is recognized upon shipment or delivery to customers, which include specialty distributors, clinical manufacturers, research organizations, and ATCs. Revenue is reduced at the time of recognition for expected chargebacks, discounts, rebates, and sales allowances, collectively referred to as gross to net adjustments, or GTN adjustments. In the U.S., these GTN adjustments are attributable to various commercial arrangements and government programs. In addition, non-U.S. government programs include different pricing schemes such as cost caps and volume discounts.

Costs and Expenses

Cost of sales

Cost of sales includes inventory and period costs, as well as non-cash expenses, related to overhead and manufacturing costs of Amtagvi®, as well as the cost of inventories and other costs, and non-cash expenses that are directly associated with the purchase and sales of Proleukin®. In addition, cost of sales includes royalties payable on sales of our products, as well as non-cash expenses including amortization of the fair value step-up of acquired Proleukin® inventory which is recognized as the acquired inventory units are sold, amortization expense for the developed technology intangible asset and the milestone payment recorded as part of the Acquisition, and the intellectual property license intangible assets.

In the event that the manufactured product does not meet specifications, or a patient is unable to receive the infusion, the Amtagvi® product is destroyed and the costs associated with manufacturing and inventory associated with the product is generally required to be expensed as cost of sales. However, if the out-of-specifications product can be administered as part of a clinical trial, in an expanded or early access program, or single-patient IND, as requested by the treating physician, the costs of the product are recorded as research and development expense based on the fact that we receive clinical data related to these infusions.

The manufacturing process for Amtagvi® is highly complex and subject to stringent FDA guidelines and requirements, as well as internal specifications and quality guidelines. Our ability to successfully manufacture Amtagvi® and deliver finished product to ATCs for infusion into patients is dependent on several factors, including patient selection and quality of tumors provided by the treatment centers for use in the manufacturing of Amtagvi®. We focus significant effort and attention on working with the treatment centers during the onboarding process regarding these matters, as well as on our internal manufacturing processes.

Research and development expense

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs, and other consulting services. Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and amortized over the period that the goods are delivered, or the related services are performed, subject to an assessment of recoverability.

Clinical development costs are a significant component of research and development expenses. We have a history of contracting with third parties that perform various clinical trial activities on our behalf in connection with the ongoing development of our product candidates. The financial terms of these contracts are subject to negotiations and may vary from contract to contract and may result in an uneven payment flow. We accrue and expense costs for clinical trial activities performed by third parties based upon estimates of work completed to date of the individual trial in accordance with agreements established with contract research organizations and clinical trial sites. The duration, costs, and timing of our clinical trials and development of our product candidates will depend on a number of factors that include, but are not limited to, the number of patients that enroll in the trial, per patient trial

costs, number of sites included in the trial, discontinuation rates of patients, duration of patient follow-up, efficacy and safety profile of the product candidate, and the length of time required to enroll eligible patients.

We expect to continue to incur research and development expenses for the foreseeable future as we continue to conduct our clinical trials for our various product candidates. We expect our research and development expenses to decrease in conjunction with an expected increase in commercial activities and selling, general, and administrative expense due to the approval of Amtagvi®. However, it is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates.

Selling, general and administrative expense

Selling, general, and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, procurement, legal, investor relations, facilities, business development, marketing, commercial, information technology and human resources functions. Other significant costs include facility costs not otherwise capitalized in inventory or included in research and development expenses, legal fees relating to corporate matters and intellectual property, insurance, public company expenses relating to maintaining compliance with Nasdaq listing rules and SEC requirements, investor relations costs, and fees for accounting and consulting services. Selling, general, and administrative costs are expensed as incurred, and we accrue for services provided by third parties related to the above expenses by monitoring the status of services provided and receiving estimates from its service providers and adjusting its accruals as actual costs become known.

We anticipate selling, general, and administrative expenses will increase as we execute the launch of Amtagvi® and market Proleukin®, as well as execute an expected expansion in the U.S. market and outside of the U.S. of the internal general and administrative team to support the overall growth in our business.

Interest and other income, net

Interest and other income, net is derived from our interest-bearing cash, cash equivalents and investment balances as well as other income associated with non-recurring activities such as lease terminations.

Income tax benefit

Income tax benefit pertains to the operations in the UK and realization of related deferred taxes.

Results of Operations for the Three Months Ended March 31, 2025 and 2024

Revenue

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Increase (Decrease) $	Increase (Decrease) %
Amtagvi®	$ 43,571	$ —	$ 43,571	100
Proleukin®	5,753	715	5,038	705
Total product revenue	$ 49,324	$ 715	$ 48,609	6,798

Revenue for the three months ended March 31, 2025 increased by $48.6 million, or 6,798%, compared to the same period in 2024. The increase was driven by the completion of the acquisition of worldwide rights to Proleukin® in May 2023, or the Acquisition, as well as the commercial launch of Amtagvi® in February 2024. Through the first quarter of 2024, product revenue was comprised entirely of product sales of Proleukin® in markets outside of the U.S. With the BLA approval of Amtagvi® in February 2024, we began generating revenue for Amtagvi® in the second quarter of 2024 as infusions occurred at our ATCs. Furthermore, in the second quarter of 2024, we began selling Proleukin® in the U.S. market. The Proleukin® inventory that was previously with distributors at the time of the Acquisition to support the U.S. market has been substantially sold, and as a result we experienced significant re-stocking demand from specialty distributors in the second half of 2024 to support ongoing and anticipated infusions related to the strong commercial launch of Amtagvi®. GTN adjustments did not materially affect net product revenue in the three months ended March 31, 2025 and 2024.

As it relates to revenue timing for our products, Amtagvi® infusions are expected to lag behind Amtagvi® related Proleukin® sales by 2-3 months, and we expect ATCs to utilize 15-18 Proleukin® vials per Amtagvi® infusion. While such Proleukin® sales are not directly indicative of future Amtagvi® revenues because of the timing of stocking activities by specialty distributors and because of sales that are not related to Amtagvi® infusions, such as sales of Proleukin® utilized in clinical manufacturing or clinical trials, such sales are one indicator of future Amtagvi® revenues.

Costs and expenses

The following table summarizes the period-over-period changes in our costs and expenses:

(in thousands)	Three Months Ended March 31,		Increase (Decrease)	
	2025	2024	$	%
Cost of sales	$ 49,741	$ 7,261	$ 42,480	585
Research and development expense	76,879	79,783	(2,904)	(4)
Selling, general, and administrative expense	43,925	31,393	12,532	40

Cost of sales

Cost of sales for the three months ended March 31, 2025 increased by $42.5 million, or 585%, compared to the same period in 2024. The increase was driven by the increase in sales of Amtagvi® and Proleukin®, as well as costs related to the manufacturing of Amtagvi®. Cost of sales included $5.4 million for the three months ended March 31, 2025, compared to $4.6 million for the three months ended March 31, 2024, of non-cash amortization expense for the developed technology intangible asset and the milestone payment recorded as part of the Acquisition as well as intellectual property license intangible assets. In addition, cost of sales included non-cash expense for the amortization of the fair value step-up of acquired Proleukin® inventory sold of $0.1 million for the three months ended March 31, 2025, compared to $0.4 million for the three months ended March 31, 2024. This expense is recorded as the units acquired in the Acquisition are sold, and we expect this amount to decrease over the next six to twelve months as this inventory is sold. In addition to the non-cash amortization expense, cost of sales included $1.3 million of royalties payable related to sales of our products in the three months ended March 31, 2025. There were no royalties payable in the three months ended March 31, 2024.

Cost of sales for the three months ended March 31, 2025 also included $15.0 million, of period costs primarily related to patient drop-off driven by patient health and ability to receive the Amtagvi® treatment, as well as manufacturing results that did not meet required specifications, and were not otherwise utilized under an expanded access program or single-patient IND to generate clinical data, resulting in manufacturing costs in the period for which we were not able to recognize revenue. In addition, to a lesser extent such costs included period costs related to overhead and manufacturing costs at the *i*CTC during the period from approval resulting from under absorption of overhead costs during the period, which was driven by our decision to launch with capacity sufficient to address anticipated commercial demand in 2024 and beyond. We continue to focus on manufacturing execution as the launch of Amtagvi® continues but expect to incur such period costs through the upcoming fiscal quarters while we continue to implement initiatives associated with manufacturing quality and until such time that we can fully utilize our manufacturing capacity.

Research and development expense

Research and development expense for the three months ended March 31, 2025 decreased by $2.9 million, or 4%, compared to the same period in 2024. The decrease was primarily attributable to a $30.5 million decrease in manufacturing costs, driven by capitalization of qualified costs for Amtagvi® manufacturing resulting from our BLA approval and the transition to commercial manufacturing to support the commercial launch of Amtagvi®. This decrease was partially offset by (i) a $16.3 million increase in payroll and related costs, including stock-based compensation, primarily driven by an increase in the number of employees (ii) a $7.5 million increase in clinical costs, driven primarily by continued enrollment in TILVANCE-301 and the resumption the LUN-202 study, and (iii) a $3.8 million increase in lab and consumable costs to develop next generation candidates.

Research and development activities are central to our business model. Product candidates in later stage 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 separate our research and development expenses into two broad categories: direct and indirect. Additionally, with respect to direct research and development expenses, we further divide expenses into the following sub-

categories: “TIL, including combination therapy,” “Next Generation,” and “Other clinical, preclinical and research programs under development.” Lifileucel monotherapy includes our TIL monotherapy clinical trials, including clinical trials previously reported as LN-145. For direct research and development expenses, we track specific project research and development expenses that are directly attributable to our preclinical and clinical development candidates that have been selected for further development. Such direct research and development expenses include third-party contract costs relating to the manufacturing of TILs, as well as preclinical and clinical trial activities.

All remaining research and development expenses are categorized as indirect research and development expenses. Such indirect research and development expenses include employee salaries and benefits, stock-based compensation, consulting and contracted services to supplement our in-house activities, and costs associated with our facilities. These expenses are not directly tied to any individual project and are generally deployed across multiple projects. As such, we do not maintain information regarding those costs incurred on a project specific basis.

The table below summarizes our research and development expenses by therapeutic area (in thousands):

	March 31,		(Decrease)	
	2025	2024	$	%
Direct research and development expense by product candidate				
TIL, including combination therapy				
Lifileucel monotherapy	$ 16,181	$ 8,812	$ 7,369	84
LN-145	-	4,338	(4,338)	(100)
Combination Therapy	3,298	4,421	(1,123)	(25)
Next Generation	1,689	4,029	(2,340)	(58)
Others clinical, preclinical, and research programs under development	7,705	2,547	5,158	203
Indirect research and development expense				
Personnel related (excluding stock-based compensation)	25,366	30,148	(4,782)	(16)
Stock-based compensation expense	9,917	9,497	420	4
Contractors and outside services	1,747	3,319	(1,572)	(47)
Office and facilities	10,976	12,672	(1,696)	(13)
Total research and development	$ 76,879	$ 79,783	$ (2,904)	(4)

Selling, general and administrative expense

Selling, general and administrative expenses for the three months ended March 31, 2025 increased by $12.5 million, or 40%, compared to the same period in 2024. The increase was primarily attributable to (i) a $7.8 million increase in payroll and related expense, including stock-based compensation, driven by an increase in headcount to support the growth in the overall business including the commercialization of Amtagvi® (ii) a $1.7 million increase in costs incurred in support of the distribution and commercialization of Amtagvi® and Proleukin®, and (iii) a $3.0 million increase in other costs, including costs associated with increased travel, software license costs related to the expansion of our information technology infrastructure and legal and professional fees.

Interest and other income, net

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Increase (Decrease) $	Increase (Decrease) %
Interest and other income, net	$ 3,220	$ 3,338	$ (118)	(4)

Interest income, net for the three months ended March 31, 2025 decreased by $0.1 million, or 4%, compared to the same period in 2024. The decrease was primarily driven by a slightly lower rate of return on our investments, partially offset by an increase in average investment balances, resulting from net proceeds from recent public and at-the-market financings.

Income tax benefit

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Increase (Decrease) $	Increase (Decrease) %
Income tax benefit	$ 1,838	$ 1,408	$ 430	31

Income tax benefit for the three months ended March 31, 2025 increased by $0.4 million, or 31%, compared to the same period in 2024. This increase was driven by the result of additional deferred tax liabilities recorded for the milestone payment made under the terms of the Acquisition and the related tax benefit from the realization of these deferred taxes for operations in the UK, and the tax benefit on deferred profit for operations in the UK.

Net loss

(in thousands)	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024	Increase (Decrease) $	Increase (Decrease) %
Net loss	$ (116,163)	$ (112,976)	$ 3,187	3

Net loss for the three months ended March 31, 2025 increased by $3.2 million, or 1%, compared to the same period in 2024. The increase in our net loss is primarily due to the related increase in cost of sales, as well as the overall growth in our workforce and corporate infrastructure to support the ongoing launch of Amtagvi® in the U.S., along with anticipated expansion in additional markets, continued growth in sales of Proleukin®, and ongoing and newly initiated clinical trials. We anticipate that we will continue to incur net losses in the future as we further invest in our clinical and internal research and development programs, as well as execution of the launch of Amtagvi®.

Liquidity and Capital Resources

As of March 31, 2025, we had $366.1 million in cash, cash equivalents, short term-investments, and restricted cash ($171.7 million of cash and cash equivalents, $188.0 million in short-term investments, and $6.4 million in restricted cash). We have incurred losses and generated negative cash flows from operations since inception. Historically, we have funded our operations from various public and private offerings of our equity securities, both common stock and preferred stock, from option and warrant exercises, and from interest income. Since 2017, our primary source of funds has been from the public sale of our common stock. With the recent approval of our BLA, we expect to continue to generate revenue from the sale of our first internally developed product, Amtagvi®. Furthermore, as Proleukin® inventory that was previously with distributors in the U.S. market at the time of the acquisition of the worldwide rights to Proleukin® in May 2023 has been substantially depleted, we also began to sell Proleukin® into the U.S. market, where product margins are substantially higher than in other markets, to support ongoing and anticipated infusions related to the continued strong commercial launch of Amtagvi®. However, such revenues for Amtagvi® and Proleukin® may not be material enough to generate positive operational cash flows during the 12 months from the date the condensed consolidated financial statements are issued and this Quarterly Report on Form 10-Q is filed.

We expect to continue to incur significant expenses to support our execution of the commercial launch of Amtagvi®, fund ongoing clinical programs, including our NSCLC registrational study, IOV-LUN-202, and our frontline advanced melanoma Phase 3 confirmatory trial, TILVANCE-301, continue the development of our pipeline candidates, and for other general corporate purposes. Based on the funds we have available as of the date our condensed consolidated financial statements for the three months ended March 31, 2025 are issued, we believe that we have sufficient capital to fund our anticipated operating expenses and capital

expenditures as planned for at least the twelve months following the issuance of our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Corporate Capitalization

As of March 31, 2025, we had outstanding 333,934,387 shares of our $0.000041666 par value common stock, 194 shares of our $0.001 par value Series A Convertible Preferred Stock, and 1,932,667 shares of our $0.001 par value Series B Convertible Preferred Stock. The outstanding shares of Series A Convertible Preferred Stock are currently convertible into 97,000 shares of our common stock, and the outstanding shares of Series B Convertible Preferred Stock are currently convertible into 1,932,667 shares of our common stock. The shares of Series A Convertible Preferred Stock and Series B Convertible Preferred Stock do not have voting rights or accrue dividends.

On June 16, 2023, we entered into a new Open Market Sale Agreement, or the 2023 Sale Agreement, with Jefferies with respect to an "at the market" offering program. Under the terms of the 2023 Sale Agreement, we may, from time to time, in our sole discretion, issue and sell up to $450.0 million of shares of our common stock pursuant to the "at the market" offering program. The 2023 Sale Agreement superseded and replaced in its entirety the 2022 Sale Agreement, which was terminated by the Company. The issuance and sale, if any, of shares of our common stock under the 2023 Sale Agreement was or will be made pursuant to a prospectus supplement dated June 16, 2023 to our Registration Statement on Form S-3ASR, which became effective immediately upon filing with the U.S. Securities and Exchange Commission on June 16, 2023. We received $301.7 million in proceeds, net of offering costs, through the sale of 44,080,226 shares of our common stock for the nine months ended September 30, 2023 through the 2022 Sale Agreement and the 2023 Sale Agreement.

On July 13, 2023, we closed an underwritten public offering of 23,000,000 shares of our common stock, which included 3,000,000 shares issued pursuant to the exercise of the option granted to the underwriters, at a public offering price of $7.50 per share, before underwriting discounts and commissions. The total net proceeds to us from the offering, including the exercise of the option by the underwriters, were $161.5 million after deducting underwriting discounts and commissions and offering expenses payable by us.

On February 22, 2024, we closed an underwritten public offering of 23,014,000 shares of our common stock at a public offering price of $9.15 per share, before underwriting discounts and commissions. The total net proceeds to us from the offering were $197.4 million after deducting underwriting discounts and commissions and offering expenses payable by us.

During the three months ended March 31, 2025, we received approximately $148.9 million in net proceeds, through the sale of 25,599,389 shares of common stock through the 2023 Sale Agreement.

In the future, we may periodically offer one or more of these securities in amounts, prices and terms to be announced when and if the securities are offered. If any of the securities covered by the 2020 Shelf Registration Statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of such offering at that time.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2025	2024
Net cash (used in) provided by:		
Operating activities	$ (103,694)	$ (122,279)
Investing activities	15,867	(111,506)
Financing activities	143,315	193,576
Net increase (decrease) in cash, cash equivalents and restricted cash*	$ 55,488	$ (40,209)

** Excludes effect of exchange rate changes*

Operating Activities

Net cash used in operating activities for the periods presented represents cash disbursements related to all activities other than investing and financing activities. Operating cash flow is derived by adjusting our net loss for non-cash items and changes in operating assets and liabilities. Net cash used in operating activities for the three months ended March 31, 2025 was $103.7 million as compared to $122.3 million for the same period in 2024. The $18.6 million increase in cash used in operating activities was driven by a $3.2 million increase in net loss resulting from increased cost of sales and overall growth in our workforce to support our expansion, partially offset by an increase in revenues generated by sales of Amtagvi® and sales of Proleukin® in the US market, as well as a net increase in non-cash charges of $6.9 million, primarily driven by higher stock-based compensation expense and amortization of intangible assets, the latter of which is driven primarily by amortization of the developed technology intangible asset recorded as part of the Acquisition and intellectual property license intangible assets associated with Amtagvi®. The increase in non-cash charges was partially offset by an increase in deferred tax benefits resulting from the realization of the related deferred taxes for operations in the UK. Further, net cash used in operating activities related to changes in operating assets and liabilities decreased by $33.1 million, driven by an increase in accounts payable and accrued expenses, resulting from timing of vendor invoicing and related payments. These decreases in the use of cash were partially offset by a $18.2 million increase driven primarily by the cash used for purchases of raw material inventory in support of the commercial demand of Amtagvi®, an increase in trade accounts receivable resulting from the sale of our products, and an increase in prepaid expenses and other assets in the current period compared to the corresponding period in 2024 that resulted from the timing of related payments, as well as the receipt of cash for other miscellaneous receivables.

Investing Activities

Net cash provided by (used in) investing activities for the periods presented primarily relates to the cash utilized to fund the Acquisition, the purchase and maturity of investments, and capital expenditures. Net cash provided by investing activities for the three months ended March 31, 2025 was $15.9 million, compared to net cash used by investing activities of $111.5 million for the same period in 2024. The decrease in cash used of $127.4 million was driven by a $76.8 million decrease associated with changes in the timing of maturities and purchases of investments, a $52.6 million decrease in cash used for the Acquisition, net of cash acquired. These decreases were offset by a $2.0 million increase in capital expenditures.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2025 was $143.3 million compared to net cash provided of $193.6 million for the same period in 2024. The decrease in net cash provided by financing activities of $50.3 million was primarily driven by a decrease in net proceeds of $49.0 million received through the sales of common stock through our “at the market” offering program during the three months ended March 31, 2025, as compared to the net proceeds received from our public offering in February 2024 in the first quarter of 2024. In addition, a $0.9 million increase in tax payments related to shares withheld for vested restricted stock units and a $0.4 million decrease in proceeds from the issuance of common stock upon the exercise of stock options and from our employee stock purchase plan program contributed to the overall decrease in cash provided by financing activities.

Contractual Obligations

The following table summarizes our non-cancellable contractual obligations as of March 31, 2025, and the effects that such obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

	Payments due by period						
	Total	2025	2026	2027	2028	2029	Thereafter
Operating lease obligations - facilities[1]	$ 87,611	$ 10,820	$ 5,490	$ 4,345	$ 4,432	$ 4,520	$ 58,004
Purchase obligations[2]	29,146	12,365	8,833	7,948	—	—	—
Total[3]	$ 116,757	$ 23,185	$ 14,323	$ 12,293	$ 4,432	$ 4,520	$ 58,004

(1) Our operating lease obligations consist of obligations under non-cancellable operating leases for our facilities in San Carlos, California, Philadelphia, Pennsylvania, and Tampa, Florida.
Excluded from the above are contractual obligations with a CMO for the manufacturing facilities and minimum fixed commitment fees included in our manufacturing contracts, such as personnel, general support fee, and minimum production or material fees. These obligations met the conditions of embedded leases under Accounting Standard Codification (ASC) Topic 842 and were included in the Operating lease liabilities in the consolidated balance sheets. However, these contracts are cancellable upon prior notice and as a result, are not included in the above table.

(2) We have purchase obligations of $29.1 million related to manufacturing and supply agreements for Proleukin® under a contract we inherited as part of the Acquisition.

(3) We acquire assets still in development and enter into research and development arrangements with third parties that often require milestone and royalty payments to the third-party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required, contingent upon the successful achievement of an important point in the development life cycle of the pharmaceutical product (*e.g.*, approval of the product for marketing by a regulatory agency). If required by the arrangement, we may have to make royalty payments based upon a percentage of the sales of the pharmaceutical product in the event that regulatory approval for marketing is obtained. Because of the contingent nature of these milestone payments, they are not included in the table of contractual obligations.
These arrangements may be material individually, and in the event that milestones for multiple products covered by these arrangements are reached in the same period, the aggregate charge to expense could be material to the results of operations in any one period. In addition, these arrangements often give us the discretion to unilaterally terminate development of the product, which would allow us to avoid making contingent payments.

Off-Balance Sheet Arrangements

As of March 31, 2025, we had no obligations that would require disclosure as off-balance sheet arrangements.

Critical Accounting Policies and Significant Judgments and Estimates

Our accounting policies are more fully described in Note 2 of the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. As described in Note 2, the preparation of our condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We base our estimates on historical experience and on various market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Estimates are assessed each period and updated to reflect current information. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our condensed consolidated financial statements:

Asset Acquisitions

We make certain judgments to determine whether transactions should be accounted for acquisitions of assets or business combinations using the guidance in Accounting Standard Codification, or ASC, Topic 805, *Business Combinations,* by first applying a screen test to assess if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further

assessment is required to determine whether we have acquired inputs and processes that have the ability to create outputs, which would meet the requirements of a business.

If the assets acquired do not constitute a business, we account for asset acquisitions using the cost accumulation and allocation method. Under this method, the cost of the acquisition, including direct acquisition-related costs, is allocated to the assets acquired on a relative fair value basis. Goodwill is not recognized in an asset acquisition and any difference between consideration transferred and the fair value of the net assets acquired is allocated to the identifiable assets acquired based on their relative fair values.

Deferred tax liabilities arising from basis differences in assets acquired are calculated using the simultaneous equations method under ASC 740, *Income Taxes* and based on the effective tax rate. The resulting deferred tax liability is recorded against the carrying amount of the acquired intangible assets on a relative fair value basis.

Contingent consideration in the scope of ASC Topic 815, *Derivatives and Hedging*, is included in the cost of the asset acquisition at its acquisition date fair value. Contingent consideration in the scope of ASC Topic 450, *Contingencies*, is recognized when it is both probable and reasonably estimable.

Intangible Assets

Our acquired intangible assets are initially measured based on an allocation of the cost of the acquisition to the assets acquired on a relative fair value basis and are recorded net of accumulated amortization, while intangible assets recorded as the result of milestone or license payments are recorded at the amount paid. We amortize our intangible assets on a straight-line basis over their estimated useful lives.

When contingent consideration is a component of the cost of an asset acquisition, we capitalize the amount of incremental cost from the contingent consideration related to the intangible asset acquired in the period the underlying contingency is resolved. When this occurs, we will recognize a cumulative catch-up to reflect amortization on the intangible assets that would have been recognized had the incremental cost from the contingent consideration been recorded as of the acquisition date.

We review intangible assets for impairment at least annually and whenever events or changes in circumstances have occurred which could indicate that the carrying value of the assets are not recoverable. If such indicators are present, we assess the recoverability of affected assets by determining if the carrying value of the assets is less than the sum of the undiscounted future cash flows of the assets. If the assets are found to not be recoverable, we measure the amount of impairment by comparing the carrying value of the assets to their fair values. We determined that no indicators of impairment existed as of March 31, 2025. No impairment of intangible assets existed as of March 31, 2025.

Inventory and Cost of Sales

Inventory is stated at the lower of cost or net realizable value on a first-in, first-out basis. Our assessment of net realizable value requires the use of estimates regarding the net realizable value of our inventory balances, including an assessment of excess or obsolete inventory. We determine excess or obsolete inventory based on multiple factors, including an estimate of recent sales forecast compared to quantities on hand and the expiration date of the product and materials.

Revenue Recognition

We recognize revenue from product sales in accordance with ASC 606, *Revenue from Contracts with Customers*. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To the extent the transaction price includes variable consideration, we estimate the amount of variable consideration that should be included in the transaction price using the most likely method based on historical experience, as well as applicable information currently available.

In the U.S., products are sold principally to hospitals and clinics, as well as distributors and wholesalers, and outside of the U.S. to hospitals and clinics. Contractual performance obligations are usually limited to transfer of control of the product to the customer. In the case of Amtagvi®, revenue is recognized upon infusion while for Proleukin®, transfer of control occurs either upon shipment or upon receipt of product after considering when the customer obtains legal title to the product. Revenue is measured as the amount of consideration we expect to receive in exchange for transferring our products and is generally based on a list of fixed prices less allowances for chargebacks, product returns, rebates and discounts. Our payment terms to customers range from 45 to 105 days; payment terms differ by customer and by product.

Revenue is reduced at the time of recognition for expected chargebacks, discounts, rebates, and sales allowances, collectively referred to as gross to net adjustments, or GTN adjustments. In the U.S., these GTN adjustments are attributable to various commercial arrangements and government programs. In addition, non-U.S. government programs include different pricing schemes such as cost caps and volume discounts. Cash discounts are recorded as a reduction to receivables and settled through the issuance of credits, typically within one month. All other GTN adjustments are recorded as a liability and settled through cash payments to the customer.

Significant judgement is required in estimating GTN adjustments considering legal interpretations of applicable laws and regulations, historical experience, payer channel mix, current contract prices under applicable programs, processing time lags and inventory levels in the distribution channel.

Indirect taxes collected from customers and remitted to government authorities that are related to sales of our products, primarily in Europe, are excluded from revenues,

Accrued Research and Development Costs

Research and development costs are expensed as incurred. Clinical development costs compose a significant component of research and development costs. We have a history of contracting with third parties, including CROs, independent clinical investigators, and CMOs, that perform various clinical trial activities on our behalf in connection with the ongoing development of our product candidates. The financial terms of these contracts are subject to negotiations and may vary from contract to contract and may result in uneven payment flow. We accrue and expense costs for clinical trial activities performed by third parties based upon the work completed to date for each clinical trial in accordance with agreements established with CROs, hospitals, and clinical investigators. Accruals for CROs and CMOs are recorded based on services received and efforts expended pursuant to agreements established with CROs, CMOs, and other outside service providers. We determine our costs through discussions with internal clinical stakeholders and outside service providers as to the progress or stage of completion of clinical trials or services and the contracted fee to be paid for such services.

Included in our clinical development costs are investigator costs, which are costs associated with treatments administered at clinical sites as required under each clinical trial protocol. Our estimates for clinical investigator costs and timing of expense recognition will depend on a number of factors that include, but are not limited to, (i) the overall number of patients that enroll in the trial at each individual site, (ii) the length of clinical trial enrollment period, (iii) discontinuation and completion rates of patients, (iv) duration of patient safety follow-ups, (v) the number of sites included in the clinical trial, and (vi) the contracted fee of each participating site for patient treatment while on clinical trial, which can vary greatly for several reasons including, but not limited to, geographic region, medical center or physician costs, and overhead costs. In addition, our estimates for per patient trial costs will vary based on a number of factors that include, but are not limited to, the extent of additional treatments that may be administered by investigators as a result of patient health status, recoverability of patient costs through insurance carriers of patients, and unanticipated cost of injuries incurred as a result of the clinical trial treatment. We accrue estimated expenses resulting from obligations under investigator site agreements as the timing of payments does not always timely align with the periods over which the treatments are administered by the clinical investigators. These estimates are typically based on contracted amounts, patient visit data, discussions with internal clinical stakeholders and outside service providers, and historical look-back analysis of actual payments made to date.

We make judgments and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to a CRO, CMO, or other outside service provider, the payments are recorded within prepaid expenses and other current assets and subsequently recognized as research and development expense when the associated services have been performed. As actual costs become known, we adjust our estimates, liabilities and assets. Inputs used in our determination of estimates discussed above may vary from actual, which will result in adjustments to research and development expense in future periods.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because a significant portion of our investments are in interest bearing investments consisting of short-term debt securities issued by the U.S. government. The primary objective of our investment activities is to preserve principal. We adhere to an investment policy that requires us to limit amounts invested in securities based on credit rating, maturity, industry group and investment type and issuer, except for securities issued by the U.S. government. We do not have any derivative financial

instruments or foreign currency instruments. As of March 31, 2025, we had $312.2 million invested in marketable securities with a maturity date of less than one year. As such we believe that we are not exposed to any material market risk. If interest rates had varied by 1% in the quarter ended March 31, 2025, the fair value of our investment portfolio would increase or decrease by approximately $0.5 million.

Inflation Risk

Inflation has not had a material effect on our business, financial condition, or results of operations as of and for the periods covered by this Quarterly Report on Form 10-Q.

Foreign currency exchange risk

In addition to our existing foreign operations, we acquired and established newly formed foreign subsidiaries to consummate our acquisition of worldwide rights in Proleukin® in the second quarter of 2023. As a result, our financial results could be significantly affected by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets in which we distribute Proleukin®. Our operating results could be exposed to changes in foreign currency exchange rates between U.S. dollar and various foreign currencies, the most significant of which is the pound sterling. When the U.S. dollar strengthens against these currencies, the relative value of sales made in the respective foreign currency decreases. Conversely, when the U.S. dollar weakens against these currencies, the relative value of such sales increase.

The majority of our product sales during the three months ended March 31, 2025 were denominated in the U.S. dollar, however, we do have some sales denominated in foreign currencies. Nevertheless, foreign currency transaction gains and losses were immaterial for the three months ended March 31, 2025. No foreign currency exchange risk existed for the three months ended March 31, 2025.

Item 4. Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures:

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q.

Changes in Internal Control Over Financial Reporting:

There have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

The information in Note 14 to the condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q is incorporated herein by reference. There are no matters which constitute material pending legal proceedings to which we are a party other than those incorporated into this item by reference from Note 14 to our condensed consolidated financial statements for the quarter ended March 31, 2025, contained in this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors

The risks described below may not be the only ones relating to our company. Additional risks that we currently believe are immaterial may also impair our business operations. Our business, financial conditions and future prospects and the trading price of our common stock could be harmed as a result of any of these risks. Investors should also refer to the other information contained or

incorporated by reference in this Quarterly Report on Form 10-Q, including our financial statements and related notes, and our other filings from time to time with the U.S. Securities and Exchange Commission, or the SEC.

Risk Factors Summary

We have marked with an asterisk (*) those risk factors below that reflect a substantive change from the risk factors included in our Annual Report on Form 10-K filed with the SEC on February 27, 2025.

Our business is subject to a number of risks and uncertainties, including those risks discussed at length below. These risks include, among others, the brief bulleted list of our principal risk factors set forth below that make an investment in our company speculative or risky. You are encouraged to carefully review our full discussion of the material risk factors relevant to an investment in our business, which follows the brief bulleted list of our principal risk factors set forth below.

Risks Related to Our Business:

- We have a history of operating losses; we expect to continue to incur losses, and we may never be profitable;
- We may need additional financing to fund our operations and complete the development of our various product candidates and commercialization of our products, and if we are unable to obtain such financing, we may be unable to complete the development of our product candidates and commercialization of our products. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates;*
- The manufacture of our products and product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we, or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure;
- Cell-based therapies and biologics rely on the availability of biological raw materials (including live cells), chemicals and agents used for manufacturing, reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For each of these, we rely or may rely on treatment sites, limited manufacturers, sole source vendors, or a limited number of vendors, which could impair our ability to manufacture and supply our products;*
- Because our current products represent, and our other potential product candidates will represent novel approaches to the treatment of disease, there are many uncertainties regarding the development, the market acceptance, third-party reimbursement coverage, and the commercial potential of our product candidates;
- No assurance can be given that the Gen 2 manufacturing process or other processes we have selected will be FDA-compliant or more efficient and will lower the cost to manufacture TIL products;
- We face significant competition from other biotechnology and pharmaceutical companies and from non-profit institutions;
- Our projections regarding the market opportunities for our products and product candidates may not be accurate, and the actual market for our products and product candidates may be smaller than we estimate;
- We have limited commercial experience and may be unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our products and product candidates, if they are approved, and as a result, we may be unable to generate significant product awareness, and the lack of awareness may limit the revenues that we generate;
- If our products or product candidates do not achieve broad market acceptance, the revenues that we generate from their sales will be limited;
- Our products and product candidates may face competition sooner than anticipated;
- As a condition of approval, the FDA and foreign regulatory authorities may require that we implement various post-marketing requirements and conduct post-marketing studies, any of which would require a substantial investment of time, effort, and money, and which may limit our commercial prospects;
- We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth;
- We may rely on third parties to perform many essential services for any products that we commercialize, including services related to distribution, government price reporting, customer service, accounts receivable management, cash collection, and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements,

our ability to commercialize our current or future products will be significantly impacted and we may be subject to regulatory sanctions;

- We may be unable to successfully or sufficiently expand our manufacturing capacity to meet demand for our products;*
- We depend on the success of our product candidates and cannot guarantee that these product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized;
- Development of a product candidate intended for use in combination with an already approved product may present more or different challenges than development of a product candidate for use as a single agent;
- A Fast Track, breakthrough therapy, or regenerative medicines advanced therapy product designations, or other designation to facilitate product candidate development may not lead to faster development or a faster regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval;
- While in the U.S. lifileucel has received orphan drug designation for melanoma stages IIB-IV and for cervical cancer patients with tumors greater than 2 cm, there is no guarantee that we will be able to maintain this designation, receive these designations for any of our other product candidates, or receive or maintain any corresponding benefits, including periods of exclusivity;
- We may encounter substantial delays in our clinical trials, not be able to conduct our clinical trials on the timelines we expect, and be required to conduct additional clinical trials or modify current or future clinical trials based on feedback we receive from the FDA and foreign regulatory authorities;
- It may take longer and cost more to complete our clinical trials than we project, or we may not be able to complete them at all;
- Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization;
- We are required to pay substantial royalties and lump sum benchmark payments under our license or acquisition agreements with the NIH, Novartis, Clinigen, and Cellectis, and we must meet certain milestones to maintain our license rights;
- We rely on and collaborate with governmental, academic, and corporate partners or agencies to approve, improve, and develop TIL cell therapies for new indications for use in combination with other therapies and to evaluate new TIL manufacturing methods, the results of which, because the manufacturing processes are not within our control, and may be incorrect or unreliable;*
- We have global operations, which expose us to additional risks, and any adverse event could have a material adverse effect on our results of operations and financial condition; and
- We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, ongoing military conflicts between Russia and Ukraine and between Israel and Hamas, Hezbollah, and the Houthis, and inflation. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine and the Middle East, geopolitical tensions, or inflation.*

Risks Related to Government Regulation:

- We are subject to extensive regulation, which can be costly and time consuming and can subject us to unanticipated delays in obtaining regulatory approvals for our products and/or product candidates, and even after obtaining regulatory approval for some of our products and/or product candidates, those products and/or product candidates may still face regulatory difficulties;
- The FDA and foreign regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates;
- Political uncertainty may have an adverse impact on our operating performance and results of operations, and uncertainty surrounding the potential legal, regulatory, and policy changes by a new U.S. presidential administration may directly affect us and the global economy;*
- Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining or maintaining regulatory approval of our product candidates in other jurisdictions; and
- Coverage and reimbursement may be limited or unavailable in certain market segments for our products or product candidates, which could make it difficult for us to sell our product candidates profitably.

The summary risk factors described above should be read together with the text of the full risk factors below in this section entitled "*Risk Factors*" and the other information set forth in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

Risks Related to Our Business

Risks Related to Our Financial Position and Need for Additional Capital

We have a history of operating losses; we expect to continue to incur losses, and we may never be profitable.

We are a commercial-stage biopharmaceutical company pioneering a transformational approach to treating cancer by harnessing the human immune system's ability to recognize and destroy diverse cancer cells using therapies personalized for each patient. Until recently, we did not have products approved for commercial sale and have not generated significant revenue from operations. We began to generate revenue from the sale of our product Amtagvi® in the second quarter of 2024. Furthermore, following the acquisition of the worldwide rights to Proleukin® in May 2023, or the Acquisition, we began to generate revenue from the sales of Proleukin®. However, Proleukin® revenues are dependent upon continued use in manufacturing and clinical settings by us and other cell therapy companies.

We recognize revenue from product sales in accordance with ASC Topic 606, Revenue from Contracts with Customers, or ASC 606. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To the extent the transaction price includes variable consideration, we estimate the amount of variable consideration that should be included in the transaction price using the most likely method based on historical experience, as well as applicable information currently available.

In the U.S., products are sold principally to hospitals and clinics, as well as distributors and wholesalers, and outside of the U.S. to hospitals and clinics. Contractual performance obligations are usually limited to transfer of control of the product to the customer. In the case of Amtagvi®, revenue is recognized upon infusion, while for Proleukin®, transfer of control occurs either upon shipment or upon receipt of the product after considering when the customer obtains legal title to the product. Revenue is measured as the amount of consideration we expect to receive in exchange for transferring our products and is generally based on a list of fixed prices less allowances for chargebacks, product returns, rebates and discounts. Our payment terms to customers range from 45 to 105 days; payment terms differ by customer and by product.

Revenue is reduced at the time of recognition for expected chargebacks, discounts, rebates, and sales allowances, collectively referred to as gross to net adjustments, or GTN adjustments. In the U.S., these GTN adjustments are attributable to various commercial arrangements and government programs. In addition, non-U.S. government programs include different pricing schemes such as cost caps and volume discounts. Cash discounts are recorded as a reduction to receivables and settled through the issuance of credits, typically within one month. All other GTN adjustments are recorded as a liability and settled through cash payments to the customer.

Significant judgement is required in estimating GTN adjustments considering legal interpretations of applicable laws and regulations, historical experience, payer channel mix, current contract prices under applicable programs, processing time lags, and inventory levels in the distribution channel.

As of March 31, 2025, we had an accumulated deficit of $2.5 billion. In addition, during the three months ended March 31, 2025, we incurred a net loss of $116.2 million. While we are executing the U.S. launch of our first internally developed product, Amtagvi®, we may not generate any meaningful product sales until later, and we expect to incur significant additional operating losses in the future as we expand our development and clinical trial activities in support of demonstrating the effectiveness of our product candidates.

Our ability to achieve long-term profitability is dependent upon obtaining regulatory approvals for our products and successfully commercializing our products alone or with third parties. However, our operations may not be profitable even if any of our products under development are successfully developed and produced and thereafter commercialized. Furthermore, our profitability and gross margins are subject to fluctuations based on factors outside of our control, such as potential additional tariffs, discussed below, as well as any changes to corporate tax rates.

We may need additional financing to fund our operations and complete the development of our various product candidates and commercialization of our products, and if we are unable to obtain such financing, we may be unable to complete the development of our product candidates and commercialization of our products. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.*

Our operations have consumed substantial amounts of cash since inception. From our inception to March 31, 2025, we have an accumulated deficit of $2.5 billion. In addition, our research and development and our operating costs have also been substantial and are expected to increase. For example, in June 2023, we entered into an open market sale agreement, or the 2023 Sale Agreement, with Jefferies, which provided for the sale of up to $450.0 million of our common stock from time to time. In February 2024, we closed another underwritten offering of our common stock. The net proceeds from the offering, after deducting the underwriting discounts and commissions and other offering expenses payable by us, were $197.4 million. As of March 31, 2025, we had $366.1 million in cash, cash equivalents, short-term investments, and restricted cash ($171.7 million of cash and cash equivalents, $188.0 million in short-term investments, and $6.4 million in restricted cash).

With the approval of the BLA, we began to generate revenue from the sale of our product Amtagvi® in the second quarter of 2024. Furthermore, following the Acquisition, we began to generate revenue from the sales of Proleukin®. There is no assurance that such funds will be sufficient to fund our operations during the 12 months from the date the condensed consolidated financial statements are issued and this Form 10-Q is filed. However, based on the funds we have available as of the date these condensed consolidated financial statements are issued, we believe that we have sufficient capital to fund our anticipated operating expenses and capital expenditures as planned for at least the next twelve months following the issuance of our condensed consolidated financial statements included in this Form 10-Q. However, in order to complete the development of our current product candidates, and in order to affect our business plan, including expanding our own manufacturing facility, we anticipate that we will have to spend more than the funds currently available to us. Furthermore, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate. We may require additional capital for the further development of our product candidates and commercialization of our products and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. Moreover, our fixed expenses such as rent, minimum payments to our contract manufacturers, and other contractual commitments, including those for our research collaborations, are substantial and are expected to increase in the future.

We will need to obtain additional financing to fund our future operations, including completing the development of our product candidates and commercialization of our products. Our future funding requirements will depend on many factors, including, but not limited to:

- progress, timing, scope, and costs of our clinical trials, including the ability to timely initiate clinical sites, enroll subjects, and manufacture TIL for treatment for patients in our ongoing, planned and potential future clinical trials;
- time and cost necessary to obtain regulatory approvals that may be required by regulatory authorities to execute clinical trials or commercialize our product;
- our ability to successfully commercialize our product candidates, if approved;
- our ability to have clinical and commercial product successfully manufactured consistent with FDA and foreign regulations, including those applicable in the EU;
- amount of sales and other revenues from product candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement for patients;
- sales and marketing costs associated with commercializing our products, if approved, including the cost and timing of building our marketing and sales capabilities;
- cost of expanding, staffing and validating our own manufacturing facility in the U.S.;
- terms and timing of our current and any potential future collaborations, licensing or other arrangements that we have established or may establish;
- cash requirements of any future acquisitions or the development of other product candidates;
- costs of operating as a public company;
- time and cost necessary to respond to technological, regulatory, political, and market developments;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- costs associated with any potential business or product acquisitions (such as the acquisition of Proleukin®), strategic collaborations, licensing agreements, or other arrangements that we may establish.

Unless and until we can generate a sufficient amount of revenue, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. Our current license and collaboration agreements may also be terminated if we are unable to meet the payment obligations under those agreements. As a result, we may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

Subject to various spending levels approved by our Board of Directors, our management will have broad discretion in the use of the net proceeds from our capital raises, including our February 2024 public offering and the proceeds from sales pursuant to our "at-the-market" sale agreement with Jefferies LLC, and may not use them effectively.

Our management will have discretion in the application of the net proceeds from our capital raises, including our recent February 2024 public offering, and the proceeds from sales pursuant to the 2023 Sale Agreement with Jefferies, which provides for the sale of up to $450.0 million of our common stock from time to time, and our stockholders will not have the opportunity as part of their investment decision to assess whether the net proceeds from our capital raises are being used appropriately. You may not agree with our decisions, and our use of the proceeds from our capital raises may not yield any return to stockholders. Because of the number and variability of factors that will determine our use of the net proceeds from our capital raises, their ultimate use may vary substantially from their currently intended use. Our failure to apply the net proceeds of our capital raises effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of those net proceeds. Stockholders will not have the opportunity to influence our decisions on how to use our net proceeds from our capital raises. Pending their use, we may invest the net proceeds from our capital raises in interest and non-interest-bearing cash accounts, short-term, investment-grade, interest-bearing instruments and U.S. government securities. These temporary investments are not likely to yield a significant return.

The use of our net operating loss carryforwards and research tax credits may be limited.

Our net operating loss carryforwards and any future research and development tax credits may expire and not be used. As of December 31, 2024, we had U.S. federal net operating loss carryforwards of approximately $1.3 billion. Our net operating loss carryforwards arising in taxable years ending on or prior to December 31, 2017 will begin expiring in 2027 if we have not used them prior to that time. Net operating loss carryforwards arising in taxable years ending after December 31, 2017, are no longer subject to expiration under the Internal Revenue Code of 1986, as amended, or the Code. Additionally, our ability to use any net operating loss and credit carryforwards to offset taxable income or tax, respectively, in the future will be limited under Sections 382 and 383 of the Code, respectively, if we have a cumulative change in ownership of more than 50% within a three-year period.

Prior to December 31, 2024, we experienced multiple ownership changes. As a result, the federal and state carryforwards associated with the net operating loss and credit deferred tax assets were reduced by the amount of tax attributes estimated to expire during their respective carryforward periods. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire. Depending on our future tax position, limitation of our ability to use net operating loss carryforwards in states in which we are subject to income tax could have an adverse impact on our results of operations and financial condition.

Recently enacted tax reform legislation in the U.S., changes to existing tax laws, or challenges to our tax positions could adversely affect our business and financial condition.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The tax rate applied is based on the estimated statutory rates in the UK as this is where our intangible assets, including our intellectual property, are domiciled, and as a result, we receive certain tax benefits. Any such changes to existing federal and state tax laws or

international and U.S. corporate tax rates could adversely impact our business, results of operations, and financial position as the impact of recent tax legislation is uncertain.

In recent years, various tax legislations were signed into law. On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was signed into law, making significant changes to the Internal Revenue Code.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted in response to the COVID-19 pandemic. Certain provisions of the CARES Act amend or suspend certain provisions of the Tax Act. For example, the tax relief measures under the CARES Act for businesses include a five-year net operating loss carryback, suspension of annual deduction limitation of 80% of taxable income from net operating losses generated in a tax year beginning after December 31, 2017, changes in the deductibility of interest, acceleration of alternative minimum tax credit refunds, payroll tax relief, and a technical correction to allow accelerated deductions for qualified improvement property. On June 15, 2020, Assembly Bill 85 was passed in California, which suspended the use of net operating losses and limited the use of credits for certain corporations. Following the change in U.S. administration, there is uncertainty regarding future legislative and regulatory changes and policies related to matters such as taxation and importation, including tariffs, and any such proposed or enacted regulations, taxes, or tariffs by the current or a future U.S. administration, Congress, or taxing and importation authorities in other jurisdictions could adversely impact the global economy and materially affect our tax obligations, tariff obligations, and operating results.

In addition, U.S. federal, state and local tax laws are extremely complex and subject to various interpretations. Although we believe that our tax estimates and positions are reasonable, including our decision to build the *i*CTC at the Navy Yard in Philadelphia in order to take advantage of the site's designation as a Keystone Opportunity Zone, Keystone Opportunity Expansion Zone, or Keystone Opportunity Improvement Zone, or collectively a KOZ, which allows incentives for business development, as well as certain other financial incentives provided by the Commonwealth of Pennsylvania, the City of Philadelphia, and the Philadelphia Industrial Development Corporation, there can be no assurance that our tax positions will not be challenged by relevant tax authorities or that we would be successful in any such challenge. Further, challenges to the site's designation as a KOZ or broader challenges to Pennsylvania's KOZ program could result in the revocation of the site's designation as a KOZ and the attendant tax advantages associated with such designation. If we are unsuccessful in such a challenge, or if the site's status as a KOZ is revoked, the relevant tax authorities may assess additional taxes, which could result in adjustments to, or impact the timing or amount of, taxable income, deductions or other tax allocations, which may adversely affect our results of operations and financial position. In addition, given our current net loss and net loss carryforwards, we may not be able to realize the full benefit of these tax advantages before they expire.

Risks Related to the Manufacturing and Commercialization of Our Products and Product Candidates

Even though our lead product Amtagvi® is approved and commercialized, we may not become profitable.

Our lead product, Amtagvi®, is initially targeting a small population of refractory patients that suffer from metastatic melanoma. Even with FDA approval of Amtagvi®, and even if we obtain significant market share, because the potential target population for Amtagvi® in refractory patients may be small, we may never achieve profitability without obtaining regulatory approval for additional indications. The FDA often approves new therapies initially only for use in patients with relapsed or refractory metastatic disease. We expect to initially seek approval of our product candidates in this setting and are currently conducting clinical trials on these patient populations. Since Proleukin® is an established product and there are competing products in development, the success of Proleukin® is closely tied to Amtagvi® and use with other cell therapies. An approval for a marketed product, such as Proleukin®, may be withdrawn by the FDA or another regulatory agency and disrupt both Proleukin® and Amtagvi® because of their codependency. Additionally, Proleukin® revenues are dependent upon continued use in manufacturing and clinical settings by Iovance and other cell therapy companies.

The manufacture of our products and product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we, or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Our products and product candidates are biologics and the process of manufacturing our products is complex, highly regulated and subject to multiple risks. The manufacture of our products and product candidates involves complex processes, including harvesting tumor fragments from patients, isolating the T cells from the tumor fragments, multiplying the T cells to obtain the desired dose, and ultimately infusing the T cells back into a patient. The complexities of manufacturing cell therapy products require extensive collaboration with treatment centers including the provision of patient tumor tissue for manufacture. Manufacturing is dependent on

many factors including quality of the patient tumor tissue, treatment center training, and unique factors specific to autologous cell therapy manufacturing that can jeopardize the product approval, launch, scale, and capacity. As a result of the complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Our manufacturing process will be susceptible to product loss or failure due to logistical issues associated with the collection of tumor fragments, or starting material, from the patient, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product, manufacturing issues associated with the differences in patient starting material, interruptions in the manufacturing process, contamination, equipment failure, assay failures, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, meeting pre-specified release criteria, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If for any reason we lose a patient's starting material, or later-developed product at any point in the process, or if any product does not meet the applicable specifications, the manufacturing process for that patient will need to be restarted, including resection of the proper amount of tumor fragment, and the resulting delay may adversely affect that patient's outcome. If microbial, viral, environmental or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Because our products and product candidates are manufactured specifically for each individual patient, we will be required to maintain a chain of identity and chain of custody with respect to the patient's tumor as it moves from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such chains of identity and chains of custody is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market. Further, as product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials or otherwise necessitate the conduct of additional studies.

Currently, our products and product candidates are manufactured at our internal facility, the *i*CTC, and by CMOs, using processes developed or modified by us or by our third-party research institution collaborators that we may not intend to use for more advanced clinical trials or commercialization. Gen 2 is the FDA-approved, commercial manufacturing process for Amtagvi® and has been selected for all ongoing and future company-sponsored clinical trials. Although we believe Gen 2 is a commercially viable process, there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, and timely availability of raw materials. As a result of these challenges, we may experience delays in our clinical development and/or commercialization plans. Furthermore, we may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

In May 2019 we entered into a lease agreement to build a commercial-scale manufacturing facility, the *i*CTC, in Philadelphia, Pennsylvania for commercial and clinical production of autologous TIL products, including our product Amtagvi®. The *i*CTC is currently manufacturing TIL for our ongoing clinical trials and Amtagvi® for commercial supply. Manufacturing performed by us is centralized at the *i*CTC, instead of manufacturing at various facilities. As of the first quarter of 2024, the *i*CTC facility was approved by the FDA for commercial manufacturing of Amtagvi®, and we successfully initiated commercial manufacturing and continue our capacity building and facility expansion activities to supply clinical and commercial TIL to meet demand. We expect our manufacturing facility will provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term margins. We have built capacity to potentially treat thousands of cancer patients annually. However, we may not be successful in finalizing the expansion of our own manufacturing facility or capability. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures, and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

The manufacture of cell therapy products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, and compliance with strictly enforced federal, state, local and foreign regulations. The FDA may take a restrictive approach when regulating cell therapy manufacturing facilities that could result in delays, product release challenges, shortages, or capacity restraints.

Our current manufacturing strategy involves the use of CMOs in conjunction with our internal manufacturing capacity at the *i*CTC. Currently our products and product candidates are manufactured internally at the *i*CTC and externally by WuXi Advanced Therapies, Inc., or Wuxi, and previously by Moffitt. Additionally, we partner with American Red Cross, or ARC, to operate our facility to produce feeder cells for TIL manufacturing. The process for manufacturing TIL is heavily reliant on the supply of biological raw materials and maintaining a GMP facility capable of supplying our manufacturing facilities with quality cells to make the final product. There are only a limited number of these types of facilities and sources for the materials needed by TIL cell therapy manufacturers. The *i*CTC and our CMO are aseptic manufacturing facilities that operate clean rooms for the production of TIL cell therapies, which are subject to contamination, labor, occupational safety, regulatory, climate, and environmental risks that could interfere with production. Any problems or delays we or our CMOs experience in preparing for commercial scale manufacturing of a product, product candidate, or component thereof may result, in the case of product candidates, a delay in the approval thereof or, in the case of products, may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development of our product candidates and commercialization of our products and could adversely affect our business. Furthermore, if we or our commercial manufacturers fail to deliver the required commercial quantities of our product candidates on a timely basis and at reasonable costs, we would likely be unable to meet demand for our products and we would lose potential revenues.

Moreover, while we are expanding our capabilities to enable more internal manufacturing, should we continue to use CMOs, we may not succeed in maintaining our relationships with our current CMO or establishing relationships with additional or alternative CMOs. Our products and product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If our CMOs should cease manufacturing for us, we would experience delays in obtaining sufficient quantities of our product candidates for clinical trials and, if approved, commercial supply. Further, our CMOs may breach, terminate, or not renew these agreements. If we were to need to find alternative manufacturing facilities it would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. The commercial terms of any new arrangement could be less favorable than our existing arrangements and the expenses relating to the transfer of necessary technology and processes could be significant.

Reliance on third-party manufacturers entails exposure to risks to which we would not be subject if we manufactured the products and product candidates exclusively by ourselves, including:

- inability to negotiate manufacturing and quality agreements with third parties under commercially reasonable terms;
- reduced day-to-day control over the manufacturing process for our product candidates as a result of using third-party manufacturers for all aspects of manufacturing activities;
- reduced control over the protection of our trade secrets and know-how from misappropriation or inadvertent disclosure;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our products and/or product candidates;
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- international or multi-national activities that are related to business activities outside of our scope, but may have an impact on a CMO's ability to conduct business in a manner consistent with governmental or our regulatory and ethical standards; and
- our ability to synchronize operations and standards to ensure that all aspects of manufacturing are consistent without deviations across facilities.

In addition, the manufacturing process and facilities for any products and product candidates that we may develop at the *i*CTC and or our CMOs is subject to FDA and foreign regulatory authority approval processes, and we or our CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. The cGMP requirements include quality control, quality assurance, and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections

by the FDA that will be conducted after we submit our marketing applications for our product candidates, including our BLAs, to the FDA. Manufacturers are also subject to continuing regulatory oversight by FDA and other regulatory authorities, including inspections following marketing approval. Further, we, in cooperation with our CMOs, must supply all necessary chemistry, manufacturing, and control documentation for a pre-approval inspection in support of a BLA on a timely basis. Although both the internal and external facilities were approved by the FDA for commercial manufacturing of Amtagvi®, there is no guarantee that we or our CMOs will be able to successfully pass all aspects of surveillance or pre-approval inspections by the FDA or other foreign regulatory authorities for Amtagvi® or future product candidates.

Our internal manufacturing facilities or our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidate that may not be detectable in final product testing. If we or our CMOs are unable to reliably produce products and/or product candidates to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products. Even after obtaining regulatory approval, in the case of our products, and even if we obtain regulatory approval, in the case of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Deviations from manufacturing requirements may further require remedial measures that may be costly and/or time-consuming for us or a third party to implement and may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

Even to the extent we use and continue to use CMOs, we are ultimately responsible for the manufacture of our products and product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in 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 biologic, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, or withdrawal of product approval.

Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations, and growth prospects.

Cell-based therapies and biologics rely on the availability of biological raw materials (including live cells), chemicals and agents used for manufacturing, reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For each of these, we rely or may rely on treatment sites, limited manufacturers, sole source vendors, or a limited number of vendors, which could impair our ability to manufacture and supply our products.*

Manufacturing our products and product candidates requires live cells among other biological raw materials, chemicals and agents used for manufacturing. Many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support clinical trials and commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing.

For each of these biological raw materials (including live cells), chemicals and agents used for manufacturing, reagents, equipment, and materials, we rely and may in the future rely on treatment sites, limited manufacturers, sole source vendors, or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, quality issues, or recently imposed tariffs which could adversely affect our ability to satisfy demand for our products or product candidates and impact our cost of goods for our products or product candidates, which in turn could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and/or commercialization plans. If such a change occurs for product candidate that is already in clinical testing, the change may require us to perform both *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

Because our current products represent, and our other potential product candidates will represent novel approaches to the treatment of disease, there are many uncertainties regarding the development, the market acceptance, third-party reimbursement coverage, and the commercial potential of our product candidates.

Human immunotherapy products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there are many uncertainties related to development, marketing, reimbursement, and the commercial potential for our product candidates. There can be no assurance as to the length of the clinical trial period, the number of patients the FDA and foreign regulatory authorities will require to be enrolled in the clinical trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these clinical trials will be acceptable to the FDA and foreign regulatory authorities to support marketing approval. The FDA may take longer than usual to come to a decision on any BLA that we submit and may ultimately determine that there is not enough data, information, or experience with our product candidates to support an approval decision. The FDA and foreign regulatory authorities may also require that we conduct additional post-marketing studies or implement risk management programs, such as Risk Evaluation and Mitigation Strategies, or REMS, until more experience with our product candidates is obtained. Finally, after increased usage, we may find that our product candidates do not have the intended effect or have unanticipated side effects, potentially jeopardizing initial or continuing regulatory approval and commercial prospects.

We may also find that the manufacture of our product candidates is more difficult than anticipated, resulting in an inability to produce a sufficient amount of our product candidates for our clinical trials or, if approved, commercial supply. Moreover, because of the complexity and novelty of our manufacturing process, there are only a limited number of manufacturers who have the capability of producing our product candidates. Should any of our contract manufacturers no longer produce our product candidates, it may take us significant time to find a replacement, if we are able to find a replacement at all.

There is no assurance that the approaches offered by our products will gain broad acceptance among doctors or patients or that governmental agencies, national healthcare systems, or third-party medical insurers will be willing to provide reimbursement coverage for proposed product candidates. Moreover, we do not have verifiable internal marketing data regarding the potential size of the commercial market for our product candidates, nor have we obtained current independent marketing surveys to verify the potential size of the commercial markets for our current product candidates or any future product candidates. Since our current product candidates and any future product candidates will represent novel approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. Accordingly, we may spend significant capital trying to obtain approval for product candidates that have an uncertain commercial market. The market for any products that we successfully develop will also depend on the selling price of the product, which may be further impacted by future price increases for our products.

Cell based therapies may not be eligible for insurance coverage due to reluctance by third party payors to cover the costs associated with such therapies. Payors may deny coverage or offer inadequate levels of reimbursement for these therapies if they determine that the product has not received appropriate clearances from the FDA or other government regulators or if they deem the therapies to be investigational or experimental, not medically necessary, or otherwise inappropriate. Although we may apply for special government programs and prepare the market for product approval, there is no way to ensure that healthcare providers,

insurance companies, or other third parties will reimburse our product at an expeditious rate. Even if we obtain insurance coverage for our product from payors, there is no guarantee that third party payors will provide adequate coverage or reimbursement. Coverage at treatment centers will require payment for the total cost of care, which includes the costs of not only our product but also the costs of surgery, conditioning chemotherapy, and other staffing and hospitalization needs. Furthermore, coverage policies and reimbursement rates are subject to change. With respect to any coverage or reimbursement that may be provided, payors may seek to impose restrictions on coverage, pricing, and reimbursement levels to contain these costs. In some cases, we do not have long-term agreements with insurance companies but negotiate single-case agreements on a case-by-case basis to obtain prior authorization, coverage, and reimbursement for a particular case. If coverage and reimbursement are not available or are inadequate, ATCs and clinics may decide not to recommend our product, and there may be a slow uptake or variable or limited access, if at all, to our therapies. Likewise, in the absence of a long-term agreement with an insurance company, there is no guarantee that an insurance company will enter into a single-case agreement with us or otherwise provide prior authorization for a particular case, in which case there may be no or inadequate coverage and reimbursement for our products. Seeking prior authorization and negotiating the single-case agreement may take anywhere from days to months to obtain, if at all, and may cause ATCs, clinics and patients to decline to use our products.

We do not yet have sufficient information to reliably estimate what it will cost to commercially manufacture our current product candidates, and the actual cost to manufacture these products could materially and adversely affect the commercial viability of these products. Our goal is to reduce the cost of manufacturing and providing our therapies. However, unless we can reduce those costs to an acceptable amount, we may never be able to develop and commercialize our product candidates. If we do not successfully develop and commercialize products based upon our approach or find suitable and economical sources for materials used in the production of our products, we will not become profitable, which would materially and adversely affect the value of our common stock.

Our TIL cell therapies and our other therapies may be provided to patients in combination with other agents provided by third parties. The cost of such combination therapy may increase the overall cost of therapy and may result in issues regarding the allocation of reimbursements between our therapy and the other agents, all of which may affect our ability to obtain reimbursement coverage for the combination therapy from governmental or private third-party medical insurers.

No assurance can be given that the Gen 2 manufacturing process or other processes we have selected will be FDA compliant or more efficient and will lower the cost to manufacture TIL products.

We have developed and are developing improved methods for generating and selecting autologous TILs, and methods for large-scale production of autologous TILs that are in accord with current cGMP procedures. We have developed a new and more efficient TIL manufacturing process that we believe can be more efficient and cost effective, and in a more automated manner than previous processes. The production and control of the physical and/or chemical attributes of our products in a cGMP facility is subject to many uncertainties and difficulties. As a novel therapy, TIL manufacturing and product release is complex and must evolve with both industry-wide autologous cell therapy challenges and new regulatory requirements that may result in delays and unexpected denials. We have limited experience in manufacturing our adoptive cell therapy product candidate on a commercial scale, as do our partners. As a result, we cannot give any assurance that the Gen 2 process or any future process that we select will be a manufacturing process that can produce our product candidates in compliance with the applicable regulatory requirements, at a cost or in quantities necessary to make them commercially viable. Moreover, we and our third-party manufacturers will have to continually adhere to current cGMP regulations enforced by the FDA and foreign regulatory authorities through facilities inspection programs. If our facilities or any of the facilities of these manufacturers cannot demonstrate adequate assurance of compliance with applicable standards during a pre-approval inspection, the approval of our products will not be granted. In complying with cGMP and foreign regulatory requirements, we and any of our third-party manufacturers will be obligated to expend time, money and effort in production, record-keeping, and quality control to assure that our products meet applicable specifications and other requirements. If we or any of our third-party manufacturers fail to comply with these requirements, we may be subject to regulatory action. No assurance can be given that we will be able to develop such a manufacturing process, or that our partners will thereafter be able to establish and operate such a production facility.

Our business entails a significant risk of product liability. If product liability lawsuits are brought against us, whether or not meritorious, we may incur substantial liabilities and may be required to limit or halt commercialization of our products and/or product candidates.

We face an inherent risk of product liability as a result of the clinical testing and manufacture of our product candidates for human trials, and we currently face an even greater risk as we commercialize products and engage in the quality testing and release of

products. For example, we may be sued if our products and/or product candidates cause, are perceived, or alleged to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale, whether or not trial participants or patients are predisposed to adverse outcomes. Furthermore, if physicians and/or hospitals are not sufficiently trained in the use of our products or therapies, whether clinical or commercialized, they may misuse or ineffectively use our products or related products for our therapies, which may result in unsatisfactory patient outcomes or patient injury. Any such product liability claims may include allegations of defects in manufacturing, defects in design, defects in quality control measures, a failure to warn of dangers inherent in the product, negligence, strict liability, and/or a breach of warranties. Claims could also be asserted under state consumer protection acts. Large judgments have also been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products and/or product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased or interrupted demand for our products and/or product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants or sites and potential termination of clinical trial sites or entire clinical programs;
- initiation of investigations by regulators (including investigation of the safety and effectiveness of our products, our manufacturing processes and facilities, or our marketing programs), refusal to approve marketing applications or supplements, warnings, and withdrawal or other limitations on product approvals;
- costs to prepare for and defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- product recalls, withdrawals, or restrictions on labeling, marketing, or promotions;
- loss of revenue;
- significant negative media attention;
- decrease in the price of our stock and overall value of our company;
- exhaustion of our available insurance coverage and our capital resources; and
- the delay or inability to commercialize our product candidates or achieve adequate revenue from our products.

Our inability to obtain sufficient product liability insurance at an acceptable cost and/or scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions and/or deductibles, and we may be subject to a product liability or bodily injury claim for which we have no coverage or for which the insurance carrier disputes the scope of coverage. Furthermore, any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. Although we currently have product liability insurance that we believe is appropriate for our stage of development, we may need to obtain higher levels to cover marketing any of our approved products. In addition, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. We anticipate that we will need to increase our insurance coverage as we commence additional clinical trials and as we commercialize product candidates that have been or may be approved. If we determine that it is prudent to increase our product liability coverage, we may be unable to obtain such increased coverage on acceptable terms, or at all. The market for insurance coverage is increasingly expensive, and the costs of insurance coverage will increase as our clinical programs and commercialization efforts increase in size. Furthermore, even if our agreements with corporate collaborators entitle us to indemnification against product liability losses, such indemnification may not be available or adequate should any claim arise.

Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources, adversely affect or eliminate the prospects for commercialization or sales of a product that is the subject of any such claim, and could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

We face significant competition from other biotechnology and pharmaceutical companies and from non-profit institutions.

Competition in the field of cancer therapy is intense and is accentuated by the rapid pace of technological development. Research and discoveries by others may result in breakthroughs which may render our products obsolete even before they generate any revenue. There are products that are approved and currently under development by others that could compete with the products that we are developing. Many of our potential competitors have substantially greater research and development capabilities and approval, manufacturing, marketing, financial, and managerial resources and experience than we do. Our competitors may:

- develop safer, more convenient or more effective immunotherapies and other therapeutic products;
- develop therapies that are less expensive or have better reimbursement from private or public payors;
- reach the market more rapidly, reducing the potential sales of our products; or
- establish superior proprietary positions.

Due to the promising clinical therapeutic effect of competitor therapies in clinical trials, we anticipate substantial direct competition from other organizations developing therapies in our commercial and pipeline target indications. In particular, we expect to compete with other new therapies for our lead indications developed by companies such as BioNtech, Bristol-Myers Squibb, Daiichi Sankyo, Eisai, Genmab, Immunocore, IO Biotech, Merck, Moderna, Pfizer, Regeneron Pharmaceuticals, and Replimune. We also may compete with other T cell therapies in development, including therapies based on genetically engineered T cell receptors rendered reactive against tumor-associated antigens prior to their administration, other genetically engineered TIL products, and TIL products designed to be reactive to specific neoantigens, by companies such as AbelZeta Pharma, Achilles Therapeutics, Adaptimmune Therapeutics, Alaunos Therapeutics, Biosyngen, GRIT Biotechnology, Immatics, Immunocore, Intima Bioscience, KSQ Therapeutics, Lyell Immunopharma, Marker Therapeutics, Obsidian Therapeutics, TILT Biotherapeutics, and others. To date, these technologies have been primarily applicable to hematologic malignancies, but their application in solid tumor indications may create competition with us. We may also face competition from immunotherapy treatments offered by companies such as Amgen, AstraZeneca, BioNTech, Bristol-Myers Squibb, Merck, Pfizer, Regeneron Pharmaceuticals, Roche, and others. We may also face competition from novel IL-2 treatments in development by Alkermes, ILToo Pharma, Merck, Nektar Therapeutics, Sanofi, Werewolf Therapeutics, and others. Many of these companies and our other current and potential competitors have substantially greater research and development capabilities and financial, scientific, regulatory, manufacturing, marketing, sales, human resources, and experience than we do. Many of our competitors have several therapeutic products that have already been developed, approved and successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the U.S. and internationally. Our competitors may obtain regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in competitors establishing a strong market position before we are able to enter the market.

Universities and public and private research institutions around the world are also potential competitors. For example, a Phase 3 M14TIL clinical trial comparing TIL to standard ipilimumab in patients with metastatic melanoma is currently being conducted in Europe by the Netherlands Cancer Institute, the Copenhagen County Herlev University Hospital, and the University of Manchester. Results from the M14TIL clinical trial were presented at the European Society for Medical Oncology Congress in September 2022. While these universities and public and private research institutions primarily have educational objectives, they may develop proprietary technologies that lead to other approved therapies by the FDA, European Commission, or other regulatory agencies, or that secure patent protection that we may need for the development of our technologies and products.

Our lead product Amtagvi® is an approved therapy for the treatment of metastatic melanoma and a candidate for the treatment of other cancers. Currently, there are numerous companies that are developing various alternate treatments for melanoma and other cancers, including patients that have progressed after prior treatment with checkpoint inhibitors and chemotherapy. Accordingly, Amtagvi® faces significant competition in the melanoma and other cancer treatment space from multiple companies. Even after obtaining regulatory approval for Amtagvi®, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our therapies. We may not be able to implement our business plan if the acceptance of our products is inhibited by price competition or the reluctance of physicians to switch from other methods of treatment to our product, or if physicians switch to other new therapies, drugs or biologic products or choose to reserve our product for use in limited circumstances.

Mergers and acquisitions in the pharmaceutical 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 acquiring technologies complementary to, or necessary for, our programs.

Our projections regarding the market opportunities for our products and product candidates may not be accurate, and the actual market for our products and product candidates may be smaller than we estimate.

Our projections of both the number of people who have the advanced cancers we are targeting, as well as the subset of people with metastatic or unresectable cancers and who have the potential to benefit from treatment with our products or product candidates are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research by third parties, and may prove to be incorrect. Further, new studies or approvals of new therapeutics may change the estimated incidence or prevalence of these cancers. The number of patients may turn

out to be lower than expected. Additionally, the potentially addressable patient population for our products and product candidates may be limited or may not be amenable to treatment with our products or product candidates and may also be limited by the cost of our treatments for patients, any future increase to such costs, and the reimbursement of those treatment costs by third-party payors. For instance, we expect Amtagvi® to initially target a small patient population that suffers from metastatic melanoma. Furthermore, we are also responsible for the manufacturing costs of products for patients that may have a tumor resection but ultimately do not receive an infusion, in which case we may incur manufacturing expenses without being able to recognize any revenue. Even if we obtain significant market share for our products or product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

We have limited commercial experience and may be unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our products and product candidates, if they are approved, and as a result, we may be unable to generate significant product awareness, and the lack of awareness may limit the revenues that we generate.

We currently have a commercial team focused on our commercial strategy, but we do not have a large commercial infrastructure for the marketing, sale, and distribution of biopharmaceutical products. In order to commercialize our products, we must continue to build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services, which will take time and require significant financial expenditures, and we may not be successful in doing so. In addition, we rely on one or more third-party distributors for the commercial sale of our products. It may be difficult to pivot from our current distributors of biopharmaceutical products in the event that any agreements with such third-party distributors are terminated. If we need to enter into alternative arrangements, this could adversely affect our business. Furthermore, even if we are able to effectively establish a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our current or future product candidates. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we would have less control over their sales efforts and could be held liable if they failed to comply with applicable legal or regulatory requirements.

In addition to marketing our product, we will need current and future ATCs both inside and outside the U.S. that are prepared and have the capacity and experience to administer our therapies to patients. Even if we are able to obtain approval for a product candidate in a country or region, we may not be able to approve enough treatment centers for the provision of our product to a broad patient population. The number of ATCs we onboard to administer our product may fluctuate and affect our product launch, and even if we onboard a large number of ATCs, this does not ensure the uptake of our products. Additionally, certain areas do not have hospitals with the facilities to safely administer our therapy. Accordingly, we may only be able to launch our products with a limited number of ATCs, which could ultimately reduce the uptake of our products. Although we have a team allocated to authorize and monitor our ATCs, substantial resources and investment from us and each treatment center may be required. Additionally, the treatment center onboarding process can be complicated and requires extensive training, technical equipment, and coordination of processes. Once authorized, ATCs will be required to ensure that their training, facilities, and treatment capabilities are adequately maintained.

We have limited prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in the building and managing of a commercial infrastructure. The establishment and development of commercial capabilities, including a comprehensive healthcare compliance program, 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, or our collaborators, will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, manage, and retain marketing, sales, and commercial support personnel. Although we have developed a commercial infrastructure, in the event we are unable to continue to develop a successful commercial infrastructure, we may not be able to commercialize our current or future product candidates, which would limit our ability to generate product revenues. Factors that may inhibit our efforts to commercialize our current or future products and product candidates and generate significant product revenues include:

- if a health epidemic or pandemic occurs it may negatively impact our ability to establish commercial operations, educate and interact with healthcare professionals, and successfully launch our product on a timely basis;
- the inability of sales personnel to obtain access to physicians or physicians do not prescribe our current or future product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs and time associated with the initial and ongoing training of sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate or any coverage and reimbursement by government and private health plans;
- 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 to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- 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.

If our products or product candidates do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

Until the closing of the Proleukin® acquisition in May 2023, we had never commercialized a product candidate for any indication. Even after our products and 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 or product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate significant product revenues or become profitable. Market acceptance of our products and 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. Physicians and their patients may likewise make decisions about therapies based on cost and insurance coverage and reimbursement. Such reimbursement may be impacted by our ability to enter into single-case agreements (in the absence of a longer term agreement) with insurance companies, and the absence of any agreement or inadequate coverage or reimbursement may require patients to pay from their own funds, but the costs of our products may be prohibitive in such cases.

Efforts to educate the medical community and third-party payors on the benefits of our products and product candidates may require significant resources and may not be successful. If any of our products or product candidates does not achieve an adequate level of market acceptance, we may not generate significant revenues, and we may not become profitable. The degree of market acceptance of any of our products and product candidates will depend on a number of factors, including:

- the efficacy of our products and product candidates;
- the prevalence and severity of adverse events associated with such products or product candidates;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the approved product's FDA-required labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for such products and product candidates;
- the relative difficulty of administration of such products and product candidates;
- cost of treatment versus economic and clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of such products and product candidates;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- distribution and use restrictions imposed by the FDA with respect to such products and product candidates or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- the timing of market introduction of such products and product candidates, as well as competitive products;
- our ability to offer such products and product candidates 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 third-party manufacturer and supplier support;
- the approval of other new products for the same indications;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors on the benefits of our products and product candidates may require significant resources and may never be successful. Even if the medical community accepts that our products and product candidates are safe and effective for their approved indications and third-party payors provide coverage and reimbursement for the same, physicians and patients may not immediately be receptive to such products or product candidates and may be slow to adopt them as an accepted treatment of the approved indications. If our current or future products and product candidates are approved but do not achieve an adequate level of acceptance among physicians, patients, and third-party payors, we may not generate meaningful revenues from our product candidates, and we may not become profitable.

Our products and product candidates may face competition sooner than anticipated.

The enactment of the Biologics Price Competition and Innovation Act, or the BPCIA, 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 biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, the FDA cannot make an approval of an application for a biosimilar product effective 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.

Our products and product candidates may qualify for the BPCIA's 12-year period of exclusivity. However, there is a risk that the FDA will not consider our products and product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not block companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Changes may also be made to this exclusivity period as a result of future legislation as there has been ongoing efforts to reduce the period of exclusivity. Even if we receive a period of BPCIA exclusivity for our first licensed product, if subsequent products do not include a modification to the structure of the product that impacts safety, purity, or potency, we may not receive additional periods of exclusivity for those products. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Medicare Part B encourages use of biosimilars by paying the provider the same percentage of the reference product, average sale price, or ASP as a mark-up, regardless of which product is reimbursed. It is also possible that payors will give reimbursement preference to biosimilars even over reference biologics absent a determination of interchangeability.

We will need to obtain approval of any proposed proprietary branded product names, and any failure or delay associated with such approval may adversely affect our business.

Any name we intend to use for our products and product candidates will require approval from the FDA and foreign regulatory authorities regardless of whether we have secured a formal trademark registration, including from the U.S. Patent and Trademark Office, or USPTO. The FDA and foreign regulatory authorities typically conduct a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA and foreign regulatory authorities may also object to a product name if they believe the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA or a foreign regulatory authority objects to any of our proposed proprietary product names, we may be required to adopt alternative names for our products and/or product candidates. If we adopt alternative names, we would lose the benefit of any existing trademark applications for such product and/or product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA and foreign regulatory authorities. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our products and product candidates.

As a condition of approval, the FDA and foreign regulatory authorities may require that we implement various post-marketing requirements and conduct post-marketing studies, any of which would require a substantial investment of time, effort, and money, and which may limit our commercial prospects.

As a condition of biologic licensing, the FDA and foreign regulatory authorities are authorized to require that sponsors of approved BLAs implement various post-market requirements, including REMS and Phase 4 studies. For example, we reached an agreement with the FDA regarding a confirmatory trial to support the conversion from accelerated to full approval of Amtagvi® in post-anti-PD-1 advanced melanoma, which we refer to as TILVANCE-301. The randomized Phase 3 TILVANCE-301 trial has been ongoing since the fourth quarter of 2022. If we receive approval of additional product candidates, the FDA and foreign regulatory authorities may determine that similar or additional post-approval requirements are necessary to ensure that our product candidates are safe, pure, and potent. To the extent that we are required to establish and implement any post-approval requirements, we will likely need to invest a significant amount of time, effort, and money. Such post-approval requirements may also limit the commercial prospects of our products and product candidates.

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

Our operations are dependent upon the services of our executives and our employees who are engaged in research and development. The loss of the services of our executive officers or senior research personnel could delay our product development programs and our research and development efforts. In order to develop our business in accordance with our business plan, we will have to hire additional qualified personnel, including in the areas of research, manufacturing, clinical trials management, regulatory affairs, and sales and marketing. We are continuing our efforts to recruit and hire the necessary employees to support our planned operations in the near term.

For example, we continue to recruit a new Chief Executive Officer. However, competition for qualified employees among companies in the biotechnology and biopharmaceutical industry is intense, and no assurance can be given that we will be able attract, hire, retain, and motivate the highly skilled employees that we need. Future growth will 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 and FDA 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 our product candidates 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. There can be no assurance that the services of these 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, compliance 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 regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring 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 our product candidates and, accordingly, may not achieve our research, development, and commercialization goals on a timely basis, or at all.

We may rely on third parties to perform many essential services for any products that we commercialize, including services related to distribution, government price reporting, customer service, accounts receivable management, cash collection, and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize our current or future products will be significantly impacted and we may be subject to regulatory sanctions.

We may retain third-party service providers to perform a variety of functions related to the sale and distribution of our current or future products, key aspects of which will be out of our direct control. These service providers may provide key services related to distribution, customer service, accounts receivable management, and cash collection. If we retain a service provider, we would substantially rely on it, as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired and we may be subject to regulatory enforcement action. Moreover, these agreements might terminate for a variety of reasons. If we fail to enter into alternative arrangements, this could further delay the commercialization of our products and adversely affect our business.

In addition, we may engage third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements related to adverse event reporting, we could be subject to regulatory sanctions.

Additionally, we may contract with a third-party to calculate and report pricing information mandated by various government programs. If a third party fails to timely report or adjust prices as required or errs in calculating government pricing information from transactional data in our financial records, it could impact our discount and rebate liability, and potentially subject us to regulatory sanctions or False Claims Act lawsuits.

We may be unable to successfully or sufficiently expand our manufacturing capacity to meet demand for our products.*

As noted above, we have limited experience in internal manufacturing our adoptive cell therapy product candidates on a commercial scale, as do our partners. We anticipate expanding internal manufacturing capacity at our *i*CTC facility and potentially at our contract manufacturer, WuXi. Scale-up of manufacturing may require additional validation studies, including capacity demonstration and/or comparability studies, each of which are subject to regulatory review, potential inspection, and approval. Moreover, while we continue to expand our internal manufacturing capacity, the current geopolitical tensions with China may impact our ability to expand manufacturing capacity at our contract manufacturer, WuXi. The Biden administration signed multiple executive orders regarding China. One particular executive order titled Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, signed on September 12, 2022, will likely impact the pharmaceutical industry to encourage U.S. domestic manufacturing of pharmaceutical products. Additionally, in February 2024, the chair and ranking member of the House Select Committee on the Chinese Communist Party, Representatives Mike Gallagher and Raja Krishnamoorthi, respectively, along with Senators Gary Peters and Bill Hagerty, sent a letter to the Biden administration requesting that both WuXi AppTec Co., Ltd., WuXi's parent company, and the affiliated WuXi Biologics be added to the Department of Defense's Chinese Military Companies List (1260H list), the Department of Commerce's Bureau of Industry and Security Entity List, and the Department of Treasury's Non-SDN Chinese Military-Industrial Complex Companies List. While the Biden administration did not take action on this letter, adding either or both previously mentioned WuXi entities on any or all of the aforementioned lists could materially impact our MSA with WuXi, and the current Trump administration could take action with regard to such letter. In addition to the recent tariffs, the new administration may also enact additional regulations or policies that affect trade with China or otherwise impact the biopharmaceutical industry by enacting laws to restrict U.S. biopharmaceutical companies from contracting with Chinese

companies on the development, research or manufacturing of biopharmaceutical products. Any additional executive orders, legislative action or potential sanctions on China could materially impact our current manufacturing partners. Finally, there have been Congressional legislative proposals, such as a bill titled the BIOSECURE Act, to discourage contracting with certain Chinese companies, including two WuXi affiliates, on the development or manufacturing of pharmaceutical products. The BIOSECURE Act passed the U.S. House of Representatives on September 9, 2024. The version of the BIOSECURE Act that passed the U.S. House of Representatives included a grandfather clause that would allow contracts entered into with the Chinese companies named therein prior to the effective date of such legislation to survive until January 1, 2032. The BIOSECURE Act did not pass the U.S. Senate before expiring, thus not becoming law, but support for the legislation remains, and the current Trump administration has promised to take a hard line on Chinese entities. While WuXi has recently entered into an agreement to be acquired by Altaris LLC, or Altaris, there is no guarantee that they will complete the transaction or that, after the transaction is completed, we will be able to continue to utilize their contract manufacturing services, as Altaris and its subsidiary Minaris Regenerative Medicine LLC, or Minaris, have limited resources and lack experience in supplying high volume commercial cell therapies for oncology indications. As a result, we may need to discontinue use of the WuXi manufacturing capacity and instead use the *i*CTC facility or other manufacturers to supply our therapies.

Regardless, any expansion of our internal and external manufacturing capability will also require us to invest substantial additional funds to hire and retain the technical personnel who have the necessary manufacturing experience. As a result, we may not be able to successfully or sufficiently increase the manufacturing capacity for our product candidates or modify our manufacturing processes. If we are unable to successfully increase the manufacturing capacity for a product candidate (as a result of lack of approval from, or capacity limitations imposed by, the FDA, or otherwise), the resulting capacity limitations could have a material adverse effect on our results of operations and financial condition. In addition, if we are unable to successfully or sufficiently increase the manufacturing capacity at the *i*CTC facility to meet demand in a timely or economic manner, or at all, we may be dependent upon the performance and capacity of third-party manufacturers. Accordingly, we face risks of capacity limitations of, difficulties with, increased costs of, and interruptions in performance by third-party manufacturers, the occurrence of which could negatively impact the availability, launch, and/or sales of our products in the future, as well as on our results of operations and financial condition. While we have agreements in place with such third-party manufacturers, 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 or quality standards could substantially harm our business. Moreover, these agreements might terminate for a variety of reasons. If we fail to enter into alternative arrangements, this could further delay our product development and adversely affect our business. For example, BI carries out the processing, manufacturing, and supply of Proleukin® pursuant to a manufacturing and supply agreement, which includes a two-year notice of termination provision. In the event that such notice of termination is given, it may be unlikely that we execute a new manufacturing and supply agreement with a manufacturer to run the processing, manufacturing, and supply of Proleukin® within that time frame.

Risks Related to the Development of Our Product Candidates

We depend on the success of our product candidates and cannot guarantee that these product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized.

We currently have two products approved for commercial sale. We have invested a significant portion of our efforts and financial resources in the development of our current product and/or product candidates, including Amtagvi®, lifileucel, and modified product candidates, IOV-4001, IOV-2001, IOV-3001, and IOV-5001, and expect that we will continue to invest heavily in our current product candidates, as well as in any future product candidates we may develop. Our business depends on the successful development and commercialization of our product candidates. Our ability to generate revenues in the future is substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize our product candidates. We currently generate no revenue from the sale of any products that are in development, and we may never be able to develop or commercialize these potential products.

Our product candidates will require additional clinical and non-clinical development, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before we generate any revenue from product sales. We cannot assure you that we will meet our timelines for our current or future clinical trials, which may be delayed or not completed for a number of reasons, including any future pandemic or epidemic. Additionally, the costs associated with development of cell therapy products may be significant due to the length of treatment and the supportive therapies provided to the patient during the treatment process. Supportive therapies may impact costs and patient viability and may potentially limit availability.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for many of our product candidates or regulatory approval that will allow us to successfully commercialize our product candidates. If we do not receive FDA approval with the necessary conditions to allow successful commercialization, and then successfully commercialize our product candidates, we will not be able to generate revenue from those product candidates in the U.S. in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates will have a material adverse impact on our business and financial condition.

Our products rely on coordination and collaboration with treatment centers that perform surgical procedures, obtain and provide lymphodepleting chemotherapy, and deliver other care to patients that are often in poor health as a result of the latter stages of cancer. This coordination of care is complicated in both the clinical trial setting and the commercial setting. Our treatment centers may not be able to obtain necessary supplies, such as lymphodepleting chemotherapy agents, because of shortages. Our commercial products and investigational therapies will rely heavily on our ability to train centers and the centers' ability to choose suitable patients and deliver a complex regimen. We may be reliant on physicians with limited experience with TIL products and the associated regimens. Although we will make efforts to train hospitals and provide processes that must be followed precisely, there is no way to ensure that all institutions will be able to perform at a high level in all aspects of the coordination of care. Patients may progress in the course of their disease or may experience serious adverse events from our products or supportive regimens while undergoing or awaiting treatment with our therapies.

Prior to our completion of a rolling BLA submission for lifileucel in March 2023 and its acceptance by the FDA in May 2023 and accelerated approval in February 2024, we had not previously submitted a BLA to the FDA, or a similar marketing application to comparable foreign authorities, for any product candidate, and we cannot be certain that our current or any future product candidates will be successful in clinical trials or receive regulatory approval. Furthermore, although we have not submitted our BLA with comparisons to existing or more established therapies and likewise do not expect the FDA to base its determination with respect to product approval on such comparisons, the FDA may factor these comparisons into its decision whether to approve our TIL cell therapies. The FDA may also consider its approvals of competing products, which may alter the treatment landscape concurrently with their review of our BLA filings, and which may lead to changes in the FDA's review requirements that have been previously communicated to us and our interpretation thereof, including changes to requirements for clinical data or clinical trial design. Such challenges and variabilities could delay approval or necessitate withdrawal of our BLA filings.

Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected adverse events or failure to achieve primary endpoints in clinical trials. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials.

If approved for marketing by applicable regulatory authorities, our ability to generate revenues from our product candidates will depend on our ability to:

- price our product candidates competitively such that third-party and government reimbursement leads to broad product adoption;
- prepare a broad network of clinical sites (*e.g.*, ATCs) for administration of our product;
- train and monitor sites for product delivery and consistent flow of appropriate patients;
- create market demand for our product candidates through our own marketing and sales activities, as well as through other arrangements with third parties marketing or selling on our behalf;
- receive regulatory approval for the targeted patient population(s) and claims that are necessary or desirable for successful marketing;
- obtain the necessary regulatory approvals to deliver the therapies to a sufficiently sized patient population;
- effectively commercialize our products;
- manufacture product candidates through CMOs or in our own manufacturing facility in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms;
- maintain patent and trade secret protection and regulatory exclusivity for our product candidates;
- launch commercial sales of our product candidates;

- maintain compliance with applicable laws, regulations, and guidance specific to commercialization, including interactions with health care professionals, patient advocacy groups, and communication of health care economic information to payors and formularies;
- achieve market acceptance of our product candidates by patients, the medical community, and third-party payors;
- obtain appropriate coverage and reimbursement for our product candidates, including at rates that will enable the market to adopt our products and enable sites to deliver the entire therapy to patients;
- partner with third party logistics providers that will successfully distribute our products;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites;
- effectively compete with other therapies or competitors; and
- following launch, ensure that our product will be used as directed and that additional unexpected safety risks will not arise.

Development of a product candidate intended for use in combination with an already approved product may present more or different challenges than development of a product candidate for use as a single agent.

Amtagvi® received accelerated approval from the FDA, and we are currently developing lifileucel in clinical trials as part of a regimen which uses lymphodepletion and IL-2. We and our collaborators are also developing TIL cell therapy along with other products, such as pembrolizumab, ipilimumab and nivolumab. The development of product candidates for use in combination with another product may present challenges. For example, 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 clinical trials could show that any positive results are attributable to the already approved product. Moreover, following product approval, the FDA may require that products used in conjunction with each other be cross labeled for combined use. Additionally, the FDA review process can be more complicated for combination products, and may result in delays, particularly if complex therapeutics are involved. To the extent that we do not have rights to already approved products, this may require us to work with another company to satisfy such a requirement. Moreover, developments related to the already approved products may impact our clinical trials for the combination, as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the approved product's safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

A Fast Track, breakthrough therapy, or regenerative medicines advanced therapy product designations, or other designation to facilitate product candidate development may not lead to faster development or a faster regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We were granted Fast Track designation by the FDA for lifileucel in metastatic melanoma and metastatic cervical cancer, as well as for lifileucel in combination with pembrolizumab in advanced melanoma. We were granted breakthrough therapy designation, or BTD, for lifileucel for metastatic cervical cancer and RMAT designation for lifileucel in advanced melanoma. We may seek Fast Track or Breakthrough designation for other of our current or future product candidates. Receipt of a designation to facilitate product candidate development is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for a designation, the FDA may disagree. In any event, the receipt of such a designation for a product candidate may not result in a faster development process, review, or approval compared to product candidates considered for approval under conventional the FDA procedures and does not assure ultimate marketing approval by the FDA. In addition, the FDA may later decide that the products no longer meet the designation conditions.

While lifileucel has received orphan drug designation for melanoma stages IIB-IV and for cervical cancer patients with tumors greater than 2 cm, there is no guarantee that we will be able to maintain this designation, receive these designations for any of our other product candidates, or receive or maintain any corresponding benefits, including periods of exclusivity.

We received orphan drug designation, or ODD, in the U.S. for lifileucel to treat malignant melanoma stages IIB-IV and cervical cancer patients with tumors greater than 2 cm. We may also seek ODD for our other product candidates, as appropriate. ODD, however, may be lost if the indication for which we develop our designated product candidates does not meet the orphan criteria. Moreover, following product approval, orphan exclusivity may be lost if the FDA determines, among other reasons, that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. Even if we obtain orphan exclusivity, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition and the same product can be approved for different conditions. Even after an orphan product is approved, the FDA can subsequently approve a product containing the same

principal molecular features for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer or more effective or makes a major contribution to patient care.

Moreover, the FDA may grant ODDs to multiple of the same products for the same indication. If another sponsor receives FDA approval for an ODD-designated product that is the same as our product candidates and intended for the same indication before we do, we would be prevented from launching our product in the U.S. for this indication for a period of at least 7 years. In response to a court decision regarding the plain meaning of the exclusivity provision of the Orphan Drug Act, the FDA may undertake a reevaluation of aspects of its orphan drug regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business, financial condition, results of operations, and prospects could be harmed.

Risks Related to Clinical Trials

We may face risks due to the need to rely on third parties, including clinical trial sites.

We are heavily reliant on third parties to conduct our clinical trials. We have a limited history of conducting clinical trials and as a company in filing and supporting the applications necessary to gain marketing approvals. 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, purity, and potency 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, applicable regulatory authorities. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Furthermore, clinical trials may be delayed or otherwise may be more difficult to execute in the future.

We have recruited a team that has experience with clinical trials and in the development of preclinical assets for translation into clinical trials; however, we as a company have limited experience completing pivotal clinical trials for cell therapy products or developing preclinical immunotherapy products. In part because of this lack of experience, we cannot be certain that our ongoing pivotal clinical trials will be completed on time, if at all, that they will progress according to our plans or expectations, or that our planned clinical trials will be initiated or initiated in a timely manner, progress according to our plans or expectations, or be completed on time, if they are completed at all.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, CMOs, or consultants. Relying on third-party clinical investigators, CROs, or CMOs may force us to encounter delays and challenges that are outside of our control. In addition to manufacturing TIL at the *i*CTC, we rely on a CMO in the U.S. and Europe to manufacture TIL for use in our clinical trials and commercial use upon approval. We may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from patients treated with products from these different facilities, or with our own manufacturing facility, in our product registrations, or to allow for use of the *i*CTC at the time of launch. Further, our CMOs may not be able to manufacture TIL or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

We rely on third party CROs and clinical trial sites to conduct, supervise, and monitor our clinical trials for our product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, independent review organizations and clinical investigators, to conduct our clinical trials. While 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 clinical trials 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, that could delay our product development activities and adversely affect our business.

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 the CROs, clinical trial sites, and other third parties do not relieve us of these oversight responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the clinical trial and for ensuring that our preclinical studies are conducted in

accordance with Good Laboratory Practices, or GLPs, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with Good Clinical Practices, or GCPs, 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 clinical trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections upon completion of a BLA filing with the FDA) of clinical trial sponsors, clinical investigators, clinical trial sites and certain third parties including CMOs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCPs, or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations.

In addition, our clinical trials must be conducted with product candidates that were produced under cGMP. Our failure to comply or our CMOs' 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 a government sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so could result in enforcement actions and adverse publicity. In the EU, revised transparency rules for clinical trials became applicable with the launch of the new Clinical Trials Information System, or CTIS. The CTIS is the online system for the regulatory submission, authorization, and supervision of clinical trials conducted in the EU/European Economic Area, or EEA, under Regulation (EU) 536/2014. Data of all clinical trials conducted in the EU/EEA – including their results – must be submitted to the CTIS and are made publicly available, unless a specific exemption applies.

Our CROs, clinical trial sites, and other third parties may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other therapeutic development activities that could harm our competitive position. In addition, these third parties are not our employees, and except for remedies available to us under our agreements with them, 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 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 clinical trials may be repeated, extended, delayed, or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, 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 may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional costs 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. Though we carefully manage our relationships with our third-party service providers, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects or results of operations.

We also rely on other third parties to manufacture and ship our products for the clinical trials that we conduct. Any performance failure on the part of these third parties could delay clinical development or marketing approval of our product candidates or commercialization of our product candidates, if approved, producing additional losses and depriving us of potential product revenue.

We may encounter substantial delays in our clinical trials, not be able to conduct our clinical trials on the timelines we expect, and be required to conduct additional clinical trials or modify current or future clinical trials based on feedback we receive from the FDA and foreign regulatory authorities.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any current or future clinical trials will be conducted as planned or completed on schedule, if at all, or that any of our product candidates will receive regulatory approval. We initiated clinical trials in patients with metastatic melanoma, cervical, head and neck, and non-small cell lung cancers, and in other indications in collaboration with third parties. We completed enrollment in the pivotal clinical trial for melanoma, C-144-01, and in June 2022, we announced that initial Cohort 4 data read by the independent review committee, or IRC,

met the primary endpoint in this clinical trial. In March 2023, we completed submission of our BLA to the FDA for the treatment of adult patients with metastatic melanoma for approval, and the FDA accepted the BLA in May 2023. We obtained BLA approval on February 16, 2024. We plan to initiate clinical trials in new indications and new cohorts in existing clinical trials. Even as these clinical trials progress, issues may arise that could require us to suspend or terminate such clinical trials or could cause the results of one cohort to differ from a prior cohort. For example, we may experience slower than anticipated enrollment in our additional pivotal clinical trials, which may consequently delay BLA submissions to the FDA or permit competitors to obtain approvals that may alter our BLA filing strategy. Additionally, temporary or permanent clinical holds could be placed on our clinical trials for a variety of reasons. For instance, on December 22, 2023, the FDA placed a clinical hold on the IOV-LUN-202 trial in response to a reported Grade 5 (fatal) serious adverse event potentially related to the non-myeloablative lymphodepletion pre-conditioning regimen, and we paused enrollment and the lifileucel treatment regimen for new patients in IOV-LUN-202 during the clinical hold. On March 4, 2024, the FDA lifted the partial clinical hold on the IOV-LUN-202 trial, permitting us to resume patient enrollment. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely initiation or completion of clinical development, or product approval include:

- regulators or IRBs may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective clinical trial site, or amend clinical trial protocols, or regulators or IRBs may require that we modify or amend our clinical trial protocols;
- delays in reaching a consensus or inability to obtain agreement with regulatory agencies on clinical trial design;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications, clinical trial design 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 may not allow us to use the clinical trial data from a research institution to support an IND if we cannot demonstrate the comparability of our product candidates with the product candidate used by the relevant research institution in its clinical trials;
- delays in or failure to reach an agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining required IRB approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold, suspensions or terminations by regulatory agencies, IRBs, or us for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a biologically or mechanistically similar therapeutic or therapeutic candidate;
- delays in recruiting suitable patients to participate in our clinical trials;
- delay in adding new investigators or clinical trial sites, or withdrawal of clinical trial sites from a clinical trial;
- delay or change in strategic direction for an indication resulting from differences in results between cohorts in a clinical trial, such as the previously disclosed preliminary results for the C-145-04 clinical trial and the final patient population and results, including differences in patient population, such as differences that might arise due to the impact of the existing immunotherapy treatment landscape, or from different interpretations of investigator results by IRC;
- failure by our CROs, clinical trial sites, patients, or other third parties, or us to adhere to clinical trial requirements, including regulatory, contractual or protocol requirements;
- failure to perform in accordance with the FDA's cGCP requirements or applicable regulatory guidelines in other countries;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate or enrollment in these clinical trials may be slower than we anticipate, potentially affecting our timelines for approval of our product candidates;
- 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 such patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;
- patients dropping out of a clinical trial;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols to regulatory authorities and IRBs, and which may cause delays in our development programs, or changes to regulatory review times;
- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our product candidates;

- changes in the standard of care on which a clinical development plan was based, which may require new or additional clinical trials;
- the cost of clinical trials of our product candidates being greater than we anticipate, or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a BLA;
- clinical trials of our product candidates producing negative or inconclusive results may fail to provide sufficient data and information to support product approval, or our studies may fail to reach the necessary level of statistical or clinical significance, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials studies, or preclinical studies, or abandon product development programs;
- early results from our clinical trials of our product candidates may be negatively affected by changes in efficacy measures such as overall response rate and duration of response as more patients are enrolled in our clinical trials or as new cohorts of our clinical trials are tested, and overall response rate and duration of response may be negatively affected by the inclusion of unconfirmed responses in preliminary results that we report if such responses are not later confirmed;
- 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;
- there may be changes to the therapeutics or their regulatory status which we are administering in combination with our product candidates;
- delays in patient enrollment due to potential health epidemics and pandemics;
- 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 FDA or comparable regulatory authorities may take longer than we anticipate when making a decision on our product candidates and prolonged government shutdowns, inadequate funding, loss of employees, changes in regulations or policies by the new U.S. administration or other disruptions may occur at the FDA, and thus, final FDA approval of our product candidates may be further delayed;
- transfer of our manufacturing processes to our CMOs or other larger-scale facilities operated by a CMO or by us and delays or failures by our CMOs or us to make any necessary changes to such manufacturing process;
- our use of different manufacturing processes within our clinical trials, including our Gen 1 and Gen 2 manufacturing processes, and any effects that may result from the use of different processes on the clinical data that we have reported and will report in the future; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing, including as a result of any quality issues associated with the contract manufacturer.

If prolonged government shutdowns, inadequate funding, loss of employees, changes in regulations or policies by the new U.S. administration or other disruptions were to occur at the FDA, final FDA approval of our product candidates may be delayed. The ability of the FDA and other government agencies to review and approve new or modified products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and SEC, have had to furlough critical employees and stop critical activities. In addition, government funding of agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Such disruptions at the FDA and other agencies may also increase the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business.

We also may conduct clinical and preclinical research in collaboration with other academic, pharmaceutical, biotechnology and biologics entities in which we combine our technologies with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the clinical trials, contract negotiations, the need to obtain agreement from multiple parties, and the necessity of obtaining additional approvals for therapeutics used in the combination clinical trials. These combination therapies will require additional testing and clinical trials will require additional regulatory approval and will increase our future cost of expenses.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing changes to our product candidates, we may be required to, or we may elect to, conduct additional studies to bridge our modified product candidates to earlier versions. These changes may require

regulatory approval or notification, may not have their desired effect, or the FDA or foreign regulatory authorities may not accept data from prior versions of the product to support an application, delaying our clinical trials or programs or necessitating additional clinical trials or preclinical studies. For example, while our first BLA submission includes our Gen 2 manufacturing process, in the future we may seek to commercialize other manufacturing processes, such as our Gen 3 manufacturing process or our PD-1 selected TIL manufacturing process. We may find that commercialization of these manufacturing processes has unintended consequences that necessitate additional development and manufacturing work or additional clinical trials and preclinical studies, or results in non-approval of a BLA.

Clinical trial delays could shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that any product candidates we may seek to develop in the future will never obtain the appropriate regulatory approvals necessary for us or any future collaborators to commence product sales. Any delay in completing development, obtaining or failure to obtain required approvals could also materially adversely affect our ability or that of any of our collaborators to generate revenue from any such product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

It may take longer and cost more to complete our clinical trials than we project, or we may not be able to complete them at all.

For budgeting and planning purposes, we have projected the date for the commencement of future clinical trials, and continuation and completion of our ongoing clinical trials. However, a number of factors, including scheduling conflicts with participating clinicians and clinical institutions, and difficulties in identifying and enrolling patients who meet clinical trial eligibility criteria, may cause significant delays. We may not commence or complete clinical trials involving any of our products as projected or may not conduct them successfully.

We are currently conducting eight company-sponsored clinical trials to assess the overall safety and efficacy of Iovance TIL monotherapy and TIL combinations in patients with melanoma, cervical, endometrial, head and neck, and lung cancers across late-line and early treatment settings, as well as our genetically modified TIL cell therapy IOV-4001 and our peripheral blood lymphocyte, or PBL, technology for hematological malignancies. However, we may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. Our ability to enroll or treat patients in our other studies, or the duration or costs of those studies, could be affected by multiple factors, including, preliminary clinical results, which may include efficacy and safety results from our ongoing Phase 2 studies, but may not be reflected in the final analyses of these clinical trials.

For example, our current clinical trials utilize an "open-label" trial design. An open-label trial is one where both the patient and investigator know whether the patient is receiving the test article or either an existing approved drug or placebo, which has the potential to create selection bias in the investigators. In our Phase 2 open-label studies, the investigators have significant discretion over the selection of patient participants. Although preliminary data from certain clinical trials were generally positive, that data may not necessarily be representative of interim or final results, as new patients are cycled through the applicable treatment regimes. As the clinical trials continue, the investigators may prioritize patients with more progressed forms of cancer than the initial patient population, based on the success or perceived success of that initial population. Patients with more progressed forms of cancer may be less responsive to treatment, and accordingly, interim efficacy data may show a decline in patient response rate or other assessment metrics. As the trials continue, investigators may shift their approach to the patient population, which may ultimately result in a decline in both interim and final efficacy data from the preliminary data, or conversely, an increase in final efficacy data following a decline in the interim efficacy data, as patients with more progressed forms of cancer are cycled out of the clinical trials and replaced by patients with less advanced forms of cancer. This opportunity for investigator selection bias in our clinical trials as a result of open-label design may not be adequately handled and may cause a decline in or distortion of clinical trial data from our preliminary results. Depending on the outcome of our open-label studies, we may need to conduct one or more follow-up or supporting studies in order to successfully develop our products for regulatory approval. Many companies in the biotechnology, pharmaceutical, and medical device industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we cannot be certain that we will not face such setbacks.

Furthermore, 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 clinical trial until its conclusion. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a clinical trial being conducted by one of our competitors. Accordingly, we cannot guarantee that the clinical trial will progress as planned or as scheduled. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing clinical trial and planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates.

We expect to rely on medical institutions, academic institutions, or CROs to conduct, supervise or monitor some or all aspects of clinical trials involving our products. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. If we fail to commence or complete, or experience delays in, any of our planned clinical trials, our stock price and our ability to conduct our business as currently planned could be harmed.

We currently anticipate that we will have to rely on our CMO to supplement the manufacturing capacity at the *i*CTC in manufacturing our adoptive cell therapy and biologic products for clinical trials. If they fail to commence or complete, or experiences delays in, manufacturing our adoptive cell therapy and other biologic products, our planned clinical trials will be delayed, which will adversely affect our stock price and our ability to conduct our business as currently planned.

Clinical trials are expensive, time-consuming and difficult to design and implement, and our clinical trial costs may be higher than for more conventional therapeutic technologies or drug products.

Clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates include candidates based on new cell therapy technologies and manufactured on a patient-by-patient basis, we expect that they will require extensive research and development and have substantial manufacturing costs. In addition, costs to treat patients with relapsed/refractory cancer and to treat potential side effects that may result from our product candidates can be significant. Some clinical trial sites may not bill, or obtain coverage from Medicare, Medicaid, or other third-party payors for some or all of these costs for patients enrolled in our clinical trials, and we may be required by those clinical trial sites to pay such costs. Accordingly, our clinical trial costs are likely to be significantly higher per patient than those of more conventional therapeutic technologies or drug products. In addition, our proposed personalized product candidates involve several complex and costly manufacturing and processing steps, the costs of which will be borne by us. We are also responsible for the manufacturing costs of products for patients that may have a tumor resection but ultimately do not receive an infusion. Depending on the number of patients that we ultimately screen and enroll in our clinical trials, and the number of clinical trials that we may need to conduct, our overall clinical trial costs may be higher than for more conventional treatments.

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

The clinical trials of our product candidates are, and the manufacturing and marketing of our products is, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test and market our product candidates. Before obtaining additional regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Because our product candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival. For example, response rates from the use of our product candidates may not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response. Regulatory authorities may ultimately disagree with our chosen endpoints or may find that our studies or clinical trial results do not support product approval. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates with small patient populations may not be predictive of the results of later-stage clinical trials or the results once the applicable clinical trials are completed. Preliminary, single cohort, or top-line results from clinical trials may not be representative of the final clinical trial results. The results of studies in one set of patients or line of treatment may not be predictive of those obtained in another and the results in various human clinical trials reported in scientific and medical literature may not be indicative of results we obtain in our clinical trials. Product candidates in later stages of clinical trials

may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Preclinical studies may also reveal unfavorable product candidate characteristics, including safety concerns.

We expect there may be greater variability in results for products processed and administered on a patient-by-patient basis, as anticipated for our product candidates, than for "off-the-shelf" products, like many other drugs. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier clinical trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

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 clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Our current and future clinical trial results may not be successful. Moreover, should there be a flaw in a clinical trial, it may not become apparent until the clinical trial is well advanced. Further, because we currently plan to test our product candidates for use with other oncology products, the design, implementation, and interpretation of the clinical trials necessary for marketing approval may be more complex than if we were developing our product candidates alone.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

We have reported preliminary results for clinical trials of our product candidates, including TIL cell therapy for the treatment of metastatic melanoma, non-small cell lung cancer, cervical cancer, and head and neck cancers. These preliminary results, which include assessments of efficacy such as ORR, are subject to substantial risk of change due to small sample sizes and may change as patients are evaluated or as additional patients are enrolled in these clinical trials. These outcomes may be unfavorable, deviate from our earlier reports, and/or delay or prevent regulatory approval or commercialization of our product candidates, including candidates for which we have reported preliminary efficacy results. In clinical trials where a staged expansion is expected, such as studies using a Simon's two stage design, these outcomes may result in the failure to meet an initial efficacy threshold for the first stage. Furthermore, other measures of efficacy for these clinical trials and product candidates may not be as favorable.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

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, or similar patients from a Phase 2 clinical trial to a pivotal program, who remain in the clinical trial until its conclusion. We may experience difficulties or delays in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the patient eligibility criteria defined in the protocol;
- the size of the clinical trial population required for analysis of the clinical trial's primary endpoints;
- the proximity of patients to clinical trial sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the efforts to facilitate timely enrollment in clinical trials and the effectiveness of recruiting publicity;
- the patient referral practices of physicians;
- competing clinical trials for similar therapies or other new therapeutics not involving cell-based immunotherapy;

- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- clinical investigators enrolling patients who do not meet the enrollment criteria, requiring the inclusion of additional patients in the clinical trial;
- health epidemics limiting our access to patients who would otherwise be eligible for enrollment, including treatment-naïve patients who may be more likely to seek standard of care therapies available at local treatment centers rather than enroll in a clinical trial at a larger hospital;
- approval of new indications for existing therapies or approval of new therapies in general;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial, return for post-treatment follow-up, or follow the required clinical trial procedures. For instance, patients, including patients in any control groups, may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition. Withdrawal of patients from our clinical trials may compromise the quality of our data.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitor's use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and approved immunotherapies, rather than enroll patients in any future clinical trial. In addition, potential enrollees may opt to participate in other clinical trials because of the length of time between the time that their tumor is resected and the TIL is infused back into the patient. Amendments to our clinical protocols may affect enrollment in, or results of, our trials, including amendments we have made to further define the patient population to be studied.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment or small population size may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates.

Our commercial product and product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us, IRBs, DSMBs, or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Even if we were to receive product approval, such approval could be contingent on inclusion of unfavorable information in our product labeling, such as limitations on the indications for use for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or requirements for costly post marketing testing and surveillance, or other requirements, including a REMS, to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of our current or future product candidates.

If unacceptable toxicities or side effects arise in the development of our product candidates, we, an IRB, DSMB, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials, order our clinical trials to be placed on clinical hold, or deny approval of our product candidates for any or all targeted indications. The FDA or comparable foreign regulatory authorities may also require additional data, clinical, or preclinical studies should unacceptable toxicities arise. We may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk/benefit perspective. Toxicities associated with our clinical trials and products may also negatively impact our ability to conduct clinical trials using TIL cell therapy in larger patient populations, such as in patients that have not yet been treated with other therapies or have not yet progressed on other therapies.

Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete our clinical trials or result in potential product liability claims. Such toxicities, which may arise from TIL cell therapy in general, including co-therapies, may include, for example, thrombocytopenia, chills, anemia, pyrexia, febrile neutropenia, diarrhea, neutropenia, vomiting, hypotension, and dyspnea. For example, the update in October 2018 from the C-144-01 clinical trial included two grade 5 treatment emergent adverse events. In addition, failure to manage toxicities, adverse events or side effects and to take recommended or other precautions may result in deaths or harm to patients. Furthermore, harm to patients may not be appropriately recognized or managed by the treating medical staff, because treatments related to personalized cell therapy are not normally encountered in the general patient population and by medical personnel. Any of these occurrences may harm our business, financial condition and prospects significantly.

We will be unable to commercialize our products if our trials are not successful.

Our research and development programs are at various stages of clinical development, including several at an early stage. We must demonstrate our products' safety and efficacy in humans through extensive clinical testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of our products, including but not limited to the following:

- safety and efficacy results in various human clinical trials reported in scientific and medical literature may not be indicative of results we obtain in our clinical trials;
- after reviewing test results, we or our collaborators may abandon projects that we might previously have believed to be promising;
- we, our collaborators or regulators, may suspend or terminate clinical trials if the participating subjects or patients are being exposed to unacceptable health risks;
- the effects our potential products have may not be the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved;
- manufacturers may not meet the necessary standards for the production of the product candidates or may not be able to supply the product candidates in a sufficient quantity;
- regulatory authorities may find that our clinical trial design or conduct does not meet the applicable approval requirements; and
- our clinical trials, as well as clinical trials from our competitors, may diminish our anticipated revenues due to overlapping patient populations, costs and payor coverage, or patient needs.

Clinical testing is very expensive, can take many years, and the outcome is uncertain. It could take as much as 12 months or more before we learn the results from any clinical trial using our adoptive cell therapy with TIL. The data collected from our clinical trials may not be sufficient to support approval by the FDA and foreign regulatory authorities of our TIL-based product candidates for the treatment of solid tumors. The clinical trials for our products under development may not be completed on schedule and the FDA and foreign regulatory authorities may not ultimately approve any of our product candidates for commercial sale. If we fail to adequately demonstrate the safety and efficacy of any product candidate under development, we may not receive regulatory approval for those products, which would prevent us from generating revenues or achieving profitability.

Risks Related to Third Parties

We may not be able to license new technology from third parties.

An element of our intellectual property portfolio is to license additional rights and technologies from third parties, including the NIH and others. Our inability to license the rights and technologies that we have identified, or that we may in the future identify, could have a material adverse impact on our ability to complete the development of our products or to develop additional products. No assurance can be given that we will be successful in licensing any additional rights or technologies from third parties, including the NIH and others. Failure to obtain additional rights and licenses may detrimentally affect our planned development of additional product candidates and could increase the cost, and extend the timelines associated with our development of such other products.

We are required to pay substantial royalties and lump sum benchmark payments under our license or acquisition agreements with the NIH, Novartis, Clinigen, and Cellectis, and we must meet certain milestones to maintain our license rights.

Under our license or acquisition agreements with the NIH, Novartis, Clinigen, and Cellectis for our adoptive cell therapy and immunotherapy technologies, we are currently required to pay both substantial benchmark payments and royalties to each entity based

on our revenues from sales of our products utilizing the licensed or acquired technologies. These payments could adversely affect the overall profitability for us of any products that we may seek to commercialize under these license agreements. In order to maintain our license rights under the NIH, Novartis, and Cellectis license agreements, we will need to meet certain specified milestones, subject to certain cure provisions, in the development of our product candidates, and a milestone payment is required to Clinigen upon the approval of lifileucel in melanoma. There is no assurance that we will be successful in meeting these milestones on a timely basis, or at all.

We are dependent on third parties to support our research, development, and supplement our internal manufacturing activities and, therefore, are subject to the efforts of these parties and our ability to successfully collaborate with these third parties.

As a result of our current strategy to supplement our internal manufacturing by outsourcing, we rely very heavily on third parties to perform for us the manufacturing of our products and/or product candidates. We also license a portion of our technology from others. We intend to rely upon both our internal facility, the *i*CTC, as well as our CMOs to produce large quantities of materials needed for clinical trials and product commercialization. Third party manufacturers may not be able to meet our needs with respect to timing, quantity, or quality. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical testing and/or commercialization efforts may be delayed, thereby delaying the submission of products for regulatory approval or the market introduction and subsequent sales of our products and product candidates. Any such delay may lower our revenues and potential profitability.

In addition, in order to supplement our own efforts to improve TIL manufacturing and develop TIL cell therapies in new indications in clinical trials, we currently work and collaborate with government and academic research institutions, medical institutions, and corporate partners such as the NCI, Moffitt, Memorial Sloan Kettering Cancer Center, Cellectis, and Novartis. We also intend to continue to enter into additional third-party collaborative agreements in the future. However, we may not be able to successfully negotiate any additional collaborative arrangements. If established, these relationships may not be scientifically or commercially successful, or may be unable to enroll patients, which has occurred in one of our prior collaborations. The success of these and future collaborations and joint development arrangements may be subject to numerous risks and uncertainties, including the inability or unwillingness of our partners to perform in the manner, or to the extent anticipated, may also be subject to disagreements regarding the rights, interests, and performance of the counterparties under our licenses and development agreements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercialization of the applicable product and/or 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 under the collaboration agreement.

With regard to future collaboration efforts, we face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for 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, an evaluation by the proposed collaborator of a number of similar or unique factors.

Collaborations with biopharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation. Any collaboration may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of product candidates and/or commercialization of products 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;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and/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;

- products and/or product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own products and/or product candidates, which may cause collaborators to cease to devote resources to the commercialization of our products and/or 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 products and/or product candidates, might lead to additional responsibilities for us with respect to products and/or 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;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborators may be involved in a business combination, resulting in the decreased emphasis or termination of development or commercialization of any product candidate subject to the collaboration agreement; and
- termination of a collaboration agreement may make it more difficult to attract new collaborators and our and our products' or product candidates' reputation in the medical, business, and financial communities could be adversely affected.

If any third-party collaborator breaches or terminates its agreement with us or fails to conduct its activities in a timely manner, the commercialization of our product candidates under development could be delayed or blocked completely. It is possible that our collaborators will change their strategic focus, pursue alternative technologies, or develop alternative products, either on their own or in collaboration with others, as a means for developing treatments for the diseases targeted by our collaborative programs. The effectiveness of our collaborators in marketing our products will also affect our revenues and earnings.

Our collaborators will also be required to comply with the applicable regulatory requirements, and, as such, are subject to the same risks as we are. If they do not or are not able to comply with these requirements, we may not be able to use the data generated through their studies to support our future investigational or marketing applications. Collaborator noncompliance may also expose them and us to regulatory enforcement actions.

No assurance can be given that we will be able to successfully collaborate with our partners as anticipated and that our current or future collaborations will be completed as contemplated, support the regulatory approval of our current product candidates, or result in any viable additional products and/or product candidates. For instance, to the extent that these collaborators conduct their studies with manufacturing processes that are different from ours or with a product that is different from ours, the results generated from their studies may not be seen in our current or future studies that employ our manufacturing processes, and the results generated from their studies may not support approval of our product candidates.

If we are unable to obtain or maintain 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 commercialization of products and/or product candidates or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

We rely on and collaborate with governmental, academic, and corporate partners or agencies to approve, improve, and develop TIL cell therapies for new indications for use in combination with other therapies and to evaluate new TIL manufacturing methods, the results of which, because the manufacturing processes are not within our control, may be incorrect or unreliable.*

In addition to our own research and process development efforts, we seek to collaborate with government, academic research institutions and corporate partners to improve TIL manufacturing and to develop TIL cell therapies for new indications. In 2020-2024, we announced our continued collaborations with the NCI, NIH, Moffitt, MDACC, and others to evaluate new solid tumor and hematologic indications for TIL cell therapy in clinical trials and preclinical studies, as well as, in some cases, new TIL manufacturing approaches. The results of these collaborations may be used to support our filing with the FDA of INDs to conduct more advanced clinical trials of our product candidates, or to otherwise analyze or make predictions or decisions with respect to our current or future product candidates. However, because the majority of our collaborations are conducted at outside laboratories and we do not have complete control over how the studies are conducted or reported or over the manufacturing methods used to manufacture TIL product, the results of such studies, which we may use as the basis for our conclusions, projections or decisions with respect to our current or future products and product candidates, may be incorrect or unreliable, or may have a negative impact on us if the results of such

studies are imputed to our products or proposed indications, even if such imputation is improper. For example, we have entered into collaborations with academic partners to perform clinical trials using TIL products that differ from our products, but the results of these clinical trials, if negative, may adversely impact our stock price and our development plans for our products. Additionally, we may use third party data to analyze, reach conclusions or make predictions or decisions with respect to our product candidates that may be incomplete, inaccurate or otherwise unreliable. There may also be delays or other limitations on our activities as a result of the inability of these entities to expedite our priorities in the product, facility, or regulatory approval process.

Other Risks Related to Our Business

Our current line of business, and the biotechnology industry in which we operate, makes it difficult to evaluate our business plan and our prospects.

We have only a limited operating history in our current line of business on which a decision to invest in our company can be based. The future of our company currently is dependent upon our ability to implement our business plan, as that business plan may be modified from time to time by our management and Board of Directors. While we believe that we have a reasonable business plan and research and development strategy, we have only a limited operating history against which we can test our plans and assumptions, and investors therefore cannot evaluate the likelihood of our success.

We face the problems, expenses, difficulties, complications, and delays normally associated with a commercial biopharmaceutical company with significant pre-commercial assets, many of which are beyond our control. Accordingly, our prospects should be considered in light of the risks, expenses, and difficulties frequently encountered in the establishment of a new business developing technologies in an industry that is characterized by a number of market entrants and intense competition. Because of our size and limited resources, we may not possess the ability to successfully overcome many of the risks and uncertainties frequently encountered by commercial biopharmaceutical companies with significant pre-commercial assets involved in the rapidly evolving field of immunotherapy. We also face the risks associated with the shift from development to commercialization of new products based on innovative technologies. There can be no assurance that we will be successful in developing our business.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized and authorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event was to occur and cause interruptions in our operations, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed.

We maintain a specialized information technology system for tracking chain of custody and chain of identity for TIL cell therapy patients. Like other autologous cell therapies, this is extremely important for patient safety and is a requirement outlined in our BLA submission. This requires us to store and maintain patient specific health information. The risks associated with storing patient health and personal data may increase cyber threats and regulatory accountability and scrutiny. Although we have industry-standard secure systems and maintain privacy controls, there is a possibility that incidents compromising this information can occur. In addition to the regulatory and civil litigation risks, failure to maintain this data correctly could result in loss of patients or impair our ability to deliver patient care.

We are dependent on information technology, systems, infrastructure and data.

We are dependent upon information technology systems, infrastructure and data. The multitude and complexity of our computer systems make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Likewise, data privacy or cybersecurity breaches by third parties, employees, contractors or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, or other business partners may be exposed to unauthorized persons or to the public. Cyberattacks are increasing in their frequency, sophistication and intensity. The Russia-Ukraine conflict may also increase cybersecurity risks on a global basis. Cyberattacks could include the deployment of harmful malware, denial-of-service, ransomware, social engineering and other means to affect service reliability and threaten data confidentiality, privacy, integrity and availability. Our business and technology partners face similar risks, and any security breach of

their systems could adversely affect our security posture. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts, or the efforts of our partners and vendors, will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other cybersecurity related breaches.

Our business could be adversely affected by the effects of health epidemics and pandemics, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.*

Our business could be adversely affected by health epidemics in regions where we have offices, manufacturing facilities, concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of clinical trial sites, third party manufacturers and CROs upon whom we rely. For example, starting in December 2019, a novel strain of coronavirus, or COVID-19, was reported to have surfaced in Wuhan, China and spread to multiple countries, including the U.S. and several European countries. In March 2020, the World Health Organization declared COVID-19 a global pandemic and the U.S. declared the COVID-19 pandemic a national emergency. Similarly, during that time, the State of California declared a state of emergency related to the spread of the COVID-19 pandemic and the health officers of six San Francisco Bay Area counties, including San Mateo County where our headquarters in San Carlos is located, issued shelter-in-place orders. In addition, on March 19, 2020, the Governor of California and the State Public Health Officer and Director of the California Department of Public Health ordered all individuals living in the State of California to stay at their place of residence for an indefinite period of time (subject to certain exceptions to facilitate authorized necessary activities) to mitigate the impact of the COVID-19 pandemic. Throughout 2020 and 2021, similar executive orders were issued by state and local governments, and states of emergency had been declared at the state and local level in most jurisdictions throughout the U.S. As recently as April 2022, ports and airports in Shanghai, China closed due to another outbreak of COVID-19, resulting in a lockdown of the city and disruption to export and import activities. In the U.S., many of these executive orders have been rescinded, however, we remain vigilant and continue to monitor any ongoing effects of the COVID-19 pandemic closely to determine if additional actions are required.

Quarantines, shelter-in-place, and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to pandemics or the spread of other infectious diseases could impact personnel at third-party manufacturing facilities in the U.S. and other countries, or the availability or cost of materials, which would disrupt our supply chain. In addition, our clinical trials may be affected by health epidemics and pandemics. Clinical site initiation, patient enrollment and patient monitoring may be delayed due to prioritization of hospital resources toward health epidemics and pandemics. Some sites may no longer be available to see patients for clinical trials. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Patients may also miss follow-up visits after receiving our therapies during our clinical trials, which may or may not be rectified by future patient visits and which may result in the exclusion of data from such patients from the clinical trial data. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to viruses that cause pandemics and epidemics, and such exposure may adversely impact our clinical trial operations. Health epidemics, may also affect our ability to recruit treatment-naïve patients into our clinical trials, because those patients may be more likely to seek standard of care therapies available at local treatment centers rather than enroll in a clinical trial at a larger hospital.

We continue to monitor the impact, if any, of health epidemics and pandemics, on our current and future operations, including our regulatory filing timelines and strategy, as well as our preparation for commercial launch. As with the COVID-19 pandemic, any restrictions regarding travel and face to face interactions or constraints on resources, either by us or our contractors, including our CMOs, may negatively impact our regulatory strategy or commercial launch preparations. Health epidemics may also impact the FDA and their ability to timely review our regulatory filings and conduct the pre-approval inspections necessary for ultimate approval of BLA. We cannot predict at this time whether and how FDA operations may be impacted at relevant times for our planned regulatory submissions.

Our failure to comply with international data protection laws and regulations could lead to government enforcement actions and significant penalties against us and adversely impact our operating results.

EU member states and other foreign jurisdictions, including Switzerland, the UK, and Canada, have adopted data protection laws and regulations which impose significant compliance obligations on us. Moreover, the collection and use of personal health data in the EU, which was formerly governed by the provisions of the EU Data Protection Directive, was replaced with the EU General

Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data.

The GDPR also imposes strict rules on the transfer of personal data out of the EU to the U.S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries. The implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. If we fail to comply with the data protection laws in any EU member country or other jurisdiction, the data protection authority of such country or other jurisdiction may, in addition to fines, impose sanctions on us, which may include a prohibition that prevents us from transferring and/or processing personal data of data subjects from such country or other jurisdiction for a duration determined by the sanctioning authority. Our inability to transfer and/or process personal data of data subjects could preclude us from conducting clinical trials of our products in the EU member country or other jurisdiction for the duration of the sanction. Our inability to conduct clinical trials in the EU member country or other jurisdiction for the duration of the sanction may delay and increase the cost of development of our products, with a material adverse effect on our business. In this regard, we expect that there will continue to be new proposed laws, regulations, and industry standards relating to privacy and data protection in the U.S., the EU, and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Our failure to comply with state and/or national data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

There are numerous other laws and legislative and regulatory initiatives at the federal and state levels addressing privacy and security concerns, and some state privacy laws apply more broadly than the Health Insurance Portability and Accountability Act (as amended by the Health Information Technology for Economic and Clinical Health Act Act), or HIPAA, and associated regulations. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020, and was recently amended and expanded by the California Privacy Rights Act, or CPRA, which will take effect on January 1, 2023. The CCPA and CPRA, among other things, create new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also created a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach.

Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context. It remains unclear what, if any, additional modifications will be made to the CPRA by the California legislature or how it will be interpreted. Therefore, the effects of the CCPA and CPRA are significant and will likely require us to modify our data processing practices and may cause us to incur substantial costs and expenses to comply.

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 or product, 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 and their existing products or product candidates and regulatory 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.

Depending on the size and nature of future strategic acquisitions, we may acquire assets or businesses that require us to raise additional capital or to operate or manage businesses in which we have limited experience. Making larger acquisitions that require us to raise additional capital to fund the acquisition will expose us to the risks associated with capital raising activities. Acquiring and thereafter operating larger new businesses will also increase our management, operating and reporting costs and burdens. 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. In addition, even if we are able to pursue certain strategic acquisition opportunities, we cannot guarantee that such acquisitions may completed in a timely manner, if at all, or that all conditions necessary to consummate such transactions will be satisfied, including the receipt of all required regulatory approvals.

We have global operations, which expose us to additional risks, and any adverse event could have a material adverse effect on our results of operations and financial condition.

Our operations outside the U.S. have recently expanded. Risks inherent in conducting a global business include:

- changes in medical reimbursement policies and programs and pricing restrictions in key markets;
- multiple regulatory requirements that could restrict our ability to manufacture and sell our products in key markets;
- trade protection measures, tariffs, and import or export licensing requirements, including the imposition of trade sanctions or similar restrictions by the U.S. or other governments;
- foreign exchange fluctuations;
- diminished protection of intellectual property in some countries; and
- possible nationalization and expropriation.

In addition, there may be changes to our business if there is instability, disruption, or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm, or disease. Events like these, such as the ongoing war between Russia and Ukraine and rising conflict in the Middle East, could result in material adverse effects on macroeconomic conditions, currency exchange rates and financial markets, and may adversely affect our business, results of operations, and financial condition.

Furthermore, changes in regulations and policies by the new U.S. administration, including increases in tariffs, and the resulting political and economic uncertainty in the U.S. may also impact our operations as well as the financial markets and the global economy.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, ongoing military conflicts between Russia and Ukraine and between Israel and Hamas, Hezbollah, and the Houthis, and inflation. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflicts in Ukraine and the Middle East, geopolitical tensions, or inflation.*

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the continuation of the military conflict between Russia and Ukraine. On February 24, 2022, a full-scale military invasion of Ukraine by Russian troops was reported. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions, and changes in inflation. We are continuing to monitor inflation, the situation in Ukraine, and global capital markets, and assessing the potential impacts on our business.

The global economy has been, and may continue to be, negatively impacted by Russia’s invasion of Ukraine. As a result of Russia’s invasion of Ukraine, the U.S., the EU, the UK, and other G7 countries, among other countries, have imposed substantial

financial and economic sanctions on certain industry sectors and parties in Russia. Broad restrictions on exports to Russia have also been imposed. These measures include: (i) comprehensive financial sanctions against major Russian banks; (ii) additional designations of Russian individuals with significant business interests and government connections; (iii) designations of individuals and entities involved in Russian military activities; and (iv) enhanced export controls and trade sanctions limiting Russia's ability to import various goods. Russian military actions and the resulting sanctions could continue to adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds.

In addition, on October 7, 2023, Hamas militants and members of other terrorist organizations infiltrated Israel's southern border from the Gaza Strip and conducted a series of terror attacks on civilian and military targets. Thereafter, Hamas launched extensive rocket attacks on Israeli population and industrial centers located along the Israeli border with the Gaza Strip. Shortly following the attack, Israel's security cabinet declared war against Hamas and launched an aerial bombardment of various targets within the Gaza Strip. The Israeli government subsequently called for the evacuation of over one million residents of the northern part of the Gaza Strip and began a ground invasion of the Gaza Strip that remains ongoing. Other terrorist and/or regional organizations have joined the hostilities as well, including Hezbollah in Lebanon, and the Houthis in Yemen, and it is possible that Palestinian military organizations in the West Bank will also join, resulting in a further widening of the conflict. The intensity and duration of Israel's current wars are difficult to predict as are such wars' economic implications on the global economy.

There are also current geopolitical tensions with China. Recently, the Biden administration has signed multiple executive orders regarding China. One particular executive order titled Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, signed on September 12, 2022, will likely impact the pharmaceutical industry to encourage U.S. domestic manufacturing of pharmaceutical products. Additionally, on February 28, 2024, President Biden signed Executive Order 14117 ("Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern") which implements a new framework to protect the privacy of personal data shared between the U.S. and Europe, which may, in effect, impact privacy laws with "countries of concern" such as China or Russia. Moreover, there have been Congressional legislative proposals, such as the bill titled the BIOSECURE Act, to discourage contracting with Chinese companies, including two WuXi affiliates, on the development or manufacturing of pharmaceutical products. The BIOSECURE Act did not pass in 2024, but support for the policies contained therein remains broad in Congress, and the bill could be reintroduced in 2025. Any additional executive action, legislative action, or potential sanctions with respect to China could materially impact our current manufacturing partners and our agreements with them, including our MSA with WuXi. For example, in February 2024, the chair and ranking member of the House Select Committee on the Chinese Communist Party, Representatives Mike Gallagher and Raja Krishnamoorthi, respectively, along with Senators Gary Peters and Bill Hagerty sent a letter to the Biden administration requesting that both WuXi AppTec Co., Ltd., WuXi's parent company, and the affiliated WuXi Biologics be added to the Department of Defense's Chinese Military Companies List (1260H list), the Department of Commerce's Bureau of Industry and Security Entity List, and the Department of Treasury's Non-SDN Chinese Military-Industrial Complex Companies List. While the Biden administration did not take action on this letter, adding either or both previously mentioned WuXi entities on any or all of the aforementioned lists could materially impact our MSA with WuXi, and the current Trump administration could take action with regard to such letter. In addition to the recent tariffs, the new administration may also enact additional regulations or policies that affect trade with China or otherwise impact the biopharmaceutical industry by enacting laws to restrict U.S. biopharmaceutical companies from contracting with Chinese companies on the development, research or manufacturing of biopharmaceutical products. Any additional executive orders, legislative action or potential sanctions on China could materially impact our current manufacturing partners.

Although our business has not been materially impacted by the ongoing military conflicts between Russia and Ukraine or Israel and Hamas, Hezbollah, and the Houthis, geopolitical tensions, tariffs, or inflation to date, it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which the conflict may impact our business. The extent and duration of the conflicts in Ukraine and the Middle East, geopolitical tensions, inflation, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described herein.

We are exposed to fluctuations in currency exchange rates that could negatively impact our financial results and cash flows.

With the acquisition of Proleukin® in May 2023 and with the future commercialization of Amtagvi® in other markets, a portion of our business will be conducted outside the U.S. Furthermore, we are required to make certain future payments under the Proleukin® acquisition agreement that are denominated in non-U.S. dollars, including future deferred consideration and earnout payments based on Proleukin® sales. As such, we face exposure to adverse movements in foreign currency exchange rates, including movements in foreign currency for the future milestone payment. These exposures may change over time as business practices evolve, and they

could have a material adverse impact on our business, cash flow, results of operations, financial condition, and prospects. Our primary exposure to movements in foreign currency exchange rates currently relates to non-U.S. dollar denominated sales in Europe, the UK, and Asia, and non-U.S. dollar denominated operating expenses and certain assets and liabilities in our operating subsidiaries.

Additionally, we have entered and may enter into business development transactions, borrowings, or other financial transactions that may give rise to currency and interest rate exposure. Since we cannot, with certainty, foresee and mitigate against such adverse changes, fluctuations in currency exchange rates, interest rates, and inflation could negatively affect our business, cash flow, results of operations, financial condition, and prospects.

In order to mitigate against the adverse impact of these market fluctuations, we may from time to time enter into hedging agreements. While hedging agreements, such as currency options and forwards and interest rate swaps, may limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks may be costly and not always successful.

Climate change or legal, regulatory, or market measures to address climate change may negatively affect our business, results of operations, cash flows and prospects.

We believe that climate change has the potential to negatively affect our business and results of operations, cash flows and prospects. We are exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low-carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk), and social and human effects (such as population dislocations and harm to health and well-being) associated with climate change. These risks can be either acute (short-term) or chronic (long-term).

The adverse impacts of climate change include increased frequency and severity of natural disasters and extreme weather events such as hurricanes, tornados, wildfires (exacerbated by drought), flooding, and extreme heat. Extreme weather and sea-level rise pose physical risks to our facilities, as well as those of our suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and business interruption caused by such natural disasters and extreme weather events. Other potential physical impacts due to climate change include reduced access to high-quality water in certain regions and the loss of biodiversity, which could impact future product development. These risks could disrupt our operations and supply chains, which may result in increased costs.

New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrade of facilities to meet new building codes, and the redesign of utility systems, which could increase our operating costs, including the cost of electricity and energy used by us. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us.

Environmental, social, and governance matters may impact our business and reputation.

Governmental authorities, non-governmental organizations, customers, investors, external stakeholders, and employees are increasingly sensitive to environmental, social, and governance, or ESG, concerns, such as diversity and inclusion, climate change, water use, recyclability or recoverability of packaging, and plastic waste. This focus on ESG concerns may lead to new requirements that could result in increased costs associated with developing, manufacturing and distributing our products. Our ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for more environmentally friendly products, packaging or supplier practices, or by failure to meet such customer expectations or demand. Changes in regulations and policies of the new U.S. administration may have the effect of scaling back or halting the progress of proposed or enacted ESG-related regulations, which may also have an effect on requirements and preferences of various government agencies and external stakeholders. While we strive to improve our ESG performance, we risk negative stockholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, if we do not act responsibly, or if we are perceived to not be acting responsibly in key ESG areas, including equitable access to medicines and vaccines, product quality and safety, diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency, and addressing human capital factors in our operations. If we do not meet the ESG expectations of our investors, customers, and other stakeholders, we could experience reduced demand for our products, loss of customers, and other negative impacts on our business and results of operations.

In addition, this emphasis on environmental, social, and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations, or reporting requirements, our reputation and business could be adversely impacted.

Risks Related to Government Regulation

We are subject to extensive regulation, which can be costly and time consuming and can subject us to unanticipated delays in obtaining regulatory approvals for our products and/or product candidates, and even after obtaining regulatory approval for some of our products and/or product candidates, those products and/or product candidates may still face regulatory difficulties.

Our products, potential products, and cell processing and manufacturing activities are subject to comprehensive regulation by the FDA in the U.S. and by comparable authorities in other countries. The process of obtaining FDA and other required regulatory approvals, including foreign approvals, is expensive and often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. In addition, regulatory agencies may lack experience with our technologies and products, which may lengthen the regulatory review process, increase our development costs and delay or prevent their commercialization.

Prior to Amtagvi®, no adoptive cell therapy using a TIL product had been approved for marketing by the FDA. Consequently, there is no precedent for the successful commercialization of products based on our technologies. In addition, we have had only limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain timely FDA or foreign regulatory approvals, if at all. We have completed the process for FDA approval for one adoptive cell therapy product. We will not be able to commercialize any of our potential products until we obtain FDA or foreign regulatory approvals, and so any delay in obtaining, or inability to obtain, FDA or foreign regulatory approvals would harm our business.

If we fail to comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may face a number of regulatory consequences, including refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements, including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, debarment from receiving government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, and adverse publicity, among other adverse consequences. Additionally, we may not be able to obtain the labeling claims necessary or desirable for the promotion of our products or product candidates. We may also be required to undertake post-marketing trials. In addition, if we or others identify side effects after any of our adoptive cell therapies are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products may be required.

The FDA and foreign regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We completed our first submission of a rolling BLA to the FDA for lifileucel in March 2023. The FDA accepted our BLA for Amtagvi® for patients with advanced melanoma in May 2023 and granted lifileucel Priority Review. The FDA originally assigned November 25, 2023 as the target action date for a decision under PDUFA, however, the FDA then reassigned February 24, 2024 as the revised target action date before approving the BLA on February 16, 2024. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. Our BLA submissions and expected timelines for our product candidates are based on our interpretation of communications received from the FDA to date regarding each product candidate and are subject to revision if additional communications are received from the FDA. As such, we may experience delays with FDA approval of additional BLAs.

We are conducting registrational trials for advanced NSCLC and frontline advanced melanoma cancer with our lifileucel product candidate. These trials, which we refer to as IOV-LUN-202 Cohorts 1 and 2 in the case of advanced NSCLC and TILVANCE-301 in the case of advanced melanoma, are currently underway and have been the subject of formal FDA meetings and communications. For instance, on December 22, 2023, the FDA placed a clinical hold on the IOV-LUN-202 trial in response to a reported Grade 5 (fatal) serious adverse event potentially related to the non-myeloablative lymphodepletion pre-conditioning regimen, and we paused enrollment and the lifileucel treatment regimen for new patients in IOV-LUN-202 during the clinical hold. On March 4, 2024, the FDA lifted the partial clinical hold on the IOV-LUN-202 trial, permitting us to resume patient enrollment. Our current beliefs regarding the registration pathway for lifileucel in these indications are based on our interpretation of communications with the FDA to date and our efforts to address such communications, which may be incorrect. Our statements that the clinical trial may support a BLA submission also assume that our as-adjusted clinical trial has addressed the additional requests and feedback by

the FDA. Further, enrollment in these clinical trials may need to be further adjusted based on future feedback from the FDA, changes in the competitive environment, or other regulatory agency input. Protocol revisions may have an adverse effect on the results reported to date. Changes to implement an independent review committee and assay validation and implementation, and the data within these clinical trials may not ultimately be supportive of product approval, all of which could result in significant delays to our currently anticipated timeline for development and approval of the lifileucel product candidate or prevent their approval.

A BLA must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of cell therapies for cancer. We may also not be able to successfully utilize the BTD designation we have received for metastatic cervical cancer to successfully complete the development and commercialization of Amtagvi® for this indication. We may not be able to reach agreement with the FDA on an interpretation of outcomes from our meetings, including meetings we have held with the FDA in relation to our C-145-04 clinical trial and future meetings. In addition, as previously disclosed, Iovance began a confirmatory Phase 3 clinical trial, TILVANCE-301, of lifileucel in combination with pembrolizumab in frontline metastatic melanoma in late 2022. The FDA previously granted Fast Track Designation for lifileucel in combination with pembrolizumab for the treatment of immune checkpoint inhibitor naïve metastatic melanoma. However, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive, and lengthy, and approval may not be obtained.

We may also experience delays, including delays arising from the need to increase enrollment, in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned clinical trials;
- reaching agreement on acceptable contract terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining approval at each clinical trial site by an independent IRB, or central IRB;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- adding new clinical trial sites;
- manufacturing sufficient quantities of qualified materials under cGMP and applying them on a subject-by-subject basis for use in clinical trials; or
- timely implementing or validating changes to our manufacturing or quality control processes and methods needed to address FDA feedback.

We could also encounter delays if there are unresolved ethical issues associated with physicians enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such clinical trials are being conducted by the FDA or other regulatory authorities, or recommended for suspension or termination by DSMBs due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, including as a result of genetic editing methods, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

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

In order to market and sell our products outside the U.S., we or our third-party collaborators may be required to obtain or maintain separate marketing approvals and comply with numerous and varying regulatory requirements. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval policies and requirements may vary among jurisdictions. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions

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 U.S., including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., 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. We or our collaborators may not be able to file for regulatory approval of our product candidates in international jurisdictions or obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. The FDA or other regulatory agencies may also withdraw approval for previously approved products.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the U.S. have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory 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.

We are, and if we receive regulatory approval of our product candidates, will continue to be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require ongoing surveillance to monitor the safety and efficacy of the product candidate. Although not required for Amtagvi® or Proleukin®, it is possible in the future that the FDA may also require a REMS to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require post-approval Phase 4 studies. Moreover, 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, 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.

In addition, we, our contractors, and our collaborators are and will remain responsible for FDA compliance, including requirements related to product design, testing, clinical trials and preclinical studies approval, manufacturing processes and quality, labeling, packaging, distribution, adverse event and deviation reporting, storage, advertising, marketing, promotion, sale, import, export, submissions of safety and other post-marketing information and reports such as deviation reports, establishment registration, product listing, annual user fees, and recordkeeping for our product candidates.

We and any of our collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with 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. The cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, that the product is less effective than previously thought, problems with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing, distribution, or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- restrictions on the labeling of our product candidates, including required additional warnings, such as black box warnings, contraindications, precautions, and restrictions on the approved indication or use;
- modifications to promotional pieces;
- changes to product labeling or the way the product is administered;
- liability for harm caused to patients or subjects;
- fines, restitution, disgorgement, warning letters, untitled letters, or holds on or termination of clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;

- product seizure or detention, or refusal to permit the import or export of our product candidates;
- injunctions or the imposition of civil or criminal penalties, including imprisonment;
- FDA debarment, debarment from government contracts, and refusal of future orders under existing contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the biologic;
- FDA restrictions on manufacturing or distribution if there is an inability to trace the source of a problem due to the nature of cell therapy;
- withdrawal of regulatory approvals for the Proleukin® product;
- reputational harm; or
- the product becoming less competitive.

Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our stock price and could significantly harm our business, financial condition, results of operations, and prospects.

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

If we fail to comply with applicable healthcare and promotional laws, including fraud and abuse and information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, and prospects could be adversely affected.

As a biopharmaceutical company, we are subject to many federal and state healthcare laws, including the federal Anti-Kickback Statute, or the AKS, the federal civil and criminal False Claims Act, or the FCA, the civil monetary penalties statute, or the CMP Law, the Medicaid Drug Rebate statute and other price reporting requirements, the Veterans Health Care Act of 1992, or the VHCA, HIPAA, the Foreign Corrupt Practices Act of 1977, or FCPA, the Patient Protection and Affordable Care Act of 2010, or the ACA, and similar state laws. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid, or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse, disclosures, and patients' rights are and will be applicable to our business. If we do not comply with all applicable laws, we may be subject to enforcement by both the federal government and the states in which we conduct our business as well as by other third parties, such as patients.

We do not currently participate in the Medicaid Drug Rebate Program. If we fail to comply with the reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs because we incorrectly determined participating was not required, we could be subject to certain reimbursement requirements, penalties, sanctions, and fines, which could adversely impact our business, financial condition, results of operations, and prospects. In the event that we begin to participate in such a program, in certain circumstances, our products would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions, and fines should we be found to be in violation of any applicable obligations thereunder.

Laws and regulations require calculation and reporting of complex pricing information for prescription drugs, and compliance will require us to invest in significant resources and develop a price reporting infrastructure or depend on third parties to compute and report our drug pricing. Pricing reported to the Centers for Medicare & Medicaid Services, or CMS, must be certified. Non-compliant activities expose us to FCA risk if they result in overcharging agencies, underpaying rebates to agencies, or causing agencies to overpay providers.

If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, debarment from government contracts, refusal of orders under existing contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with

applicable laws, they may be subject to criminal, civil, or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially affect our business.

In order to obtain additional clarification on the AKS or the CMP Law, a written interpretative advisory opinion can be requested from the Department of Health and Human Services' Office of Inspector General, or OIG, regarding existing or contemplated arrangements. Advisory opinions are binding as to the OIG, but only with respect to the requesting party or parties. The advisory opinions are not binding as to other governmental agencies (e.g., the Department of Justice) and certain matters (e.g., whether certain payments made in conjunction with conduct seeking to meet certain safe harbor protections are at fair market value) are not within the purview of an advisory opinion. In 2024, the OIG issued to us a favorable advisory opinion concluding that a proposed arrangement, providing travel and lodging for certain patients and caregivers in connection with a patient's receipt of our cell therapy product, presented a sufficient low risk of fraud and abuse under the AKS and did not generate prohibited remuneration under the CMP Law. We offer travel and lodging support for patients and caregivers who meet our criteria and have structured our program in line with the OIG advisory opinion. While we believe we have properly structured our support in compliance with the AKS and the CMP Law, we cannot guarantee that the OIG or other regulators will not be able to successfully challenge our arrangements.

In particular, if we are found to have impermissibly promoted any of our product candidates, we may become subject to significant liability and government fines. We, and any of our collaborators, must comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, the OIG, and state attorneys general. Additionally, advertising and promotional activities may be scrutinized and challenged by members of Congress, competitors, healthcare professionals, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for desired uses or indications for our products and product candidates, we may not market or promote our products for those indications and uses, referred to as off-label uses, and our business may be adversely affected. We further must be able to sufficiently substantiate any claims that we make for our products 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.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA. These off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off-label use.

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 of permanent injunctions under which specified promotional conduct is changed or curtailed. Thus, we and any of our collaborators will not be able to promote any products we develop for indications or uses for which they are not approved.

In the U.S., engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes, including 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 do business through, for example, corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and debarment from government contracts and refusal of future orders under existing contracts. These false claims statutes include the federal civil FCA, which allows any individual to bring a lawsuit against a biopharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. These FCA lawsuits against manufacturers of drugs and biologics 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 or our future collaborators 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 and prospects.

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

In the EU, companies may not promote unauthorized products or therapeutic indications. Therefore, it is generally prohibited to disseminate information regarding off-label uses of medicinal products. Exceptionally, companies may provide information on unauthorized products or indications in response to a written unsolicited request by an HCP (*i.e.*, on a reactive basis only), as that is excluded from the definition of advertising under EU law. This should be done through the medical team/Medical Science Liaisons, or MSLs, and not the marketing/sales representatives. Moreover, specific rules may apply in each EU member state as regards the interactions between MSLs and HCPs.

Coverage and reimbursement may be limited or unavailable in certain market segments for our products or product candidates, which could make it difficult for us to sell our product candidates profitably.

In both domestic and foreign markets, sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care entities, private health insurers, self-insured employers, and other organizations. In addition, because our product candidates represent new approaches to the treatment of cancer for which no reimbursement rates may currently or definitively apply, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions often rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from payors is critical to new product acceptance.

Third-party payors, including government health care programs, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we, or our collaborators, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or our collaborators, to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Federal and state legislatures and agencies continue to promulgate laws and regulations impacting coverage and reimbursement of drugs and treatments. For example, on September 26, 2024, the CMS issued a final rule titled "Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program," which may impact our reimbursement and rebate strategy.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical, and cost-effectiveness data for the use of our products. Payors may refuse to provide coverage for or may deny reimbursement for a product, depending on how they view such data. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate

for us to achieve or sustain profitability. 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. Payors may require co-payments that patients find unacceptably high. Moreover, the factors noted above have continued to be the focus of policy and regulatory debate that has, thus far, shown the potential for movement towards permanent policy changes; this trend is apt to continue, and may result in more or less favorable impacts on pricing. In some cases, we do not have long-term agreements with insurance companies but negotiate single-case agreements on a case-by-case basis to obtain prior authorization, coverage, and reimbursement for a particular case. Likewise, in the absence of a long-term agreement with an insurance company, there is no guarantee that an insurance company will enter into a single-case agreement with us or otherwise provide prior authorization for a particular case, in which case there may be no or inadequate coverage and reimbursement for our products. Seeking prior authorization and negotiating the single-case agreement may take anywhere from days to months to obtain, if at all, and may cause ATCs, clinics, and patients to decline to use our products.

Providers may be unlikely to prescribe, and patients may be unlikely to use our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our product candidates. This effort may include post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals and 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 future 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 the U.S., 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 and from jurisdiction to jurisdiction. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific, clinical, and cost-effectiveness data to support the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. In the EU, each member state is responsible for establishing the price and reimbursement conditions of medicinal products placed in its market.

Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers are subject to price controls, including ceilings, and private institutions obtain discounts through group purchasing organizations. Net prices for drugs may be further reduced by mandatory discounts or rebates required by government healthcare programs and demanded by private payors. It is also not uncommon for market conditions to warrant multiple discounts to different customers on the same unit, such as purchase discounts to institutional care providers and rebates to the health plans that pay them, which reduces the net realization on the original sale.

In addition, federal programs impose penalties on manufacturers of drugs marketed under an NDA or BLA, in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. Regulatory authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of our collaborators to sell our product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of our collaborators, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost control initiatives could cause us, or our collaborators, to decrease, discount, or rebate a portion of the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the realized prices for our products, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects to generate revenue and achieve profitability will decline. Moreover, recent and ongoing series of congressional hearings relating to drug pricing has presented heightened attention to the biopharmaceutical industry, creating the potential for political and public pressure. The potential for resulting legislative or policy changes presents uncertainty.

Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. If payors subject our product candidates to maximum payment amounts or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may decline prescriptions and seek alternative therapies. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals and 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 future 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.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We, and our collaborators, cannot be sure that coverage will be available for any product candidate that we, or they, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any 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.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. A particular challenge for our product candidates arises from the fact that they will primarily be used in an inpatient setting. Inpatient reimbursement generally relies on stringent packaging rules that may mean that there is no separate payment for our product candidates. Additionally, data used to set the payment rates for inpatient admissions is usually several years old and would not take into account all of the additional therapy costs associated with the administration of our product candidates. If special rules are not created for reimbursement for immunotherapy treatments such as our product candidates, hospitals might not receive enough reimbursement to cover their costs of treatment, which will have a negative effect on their adoption of our product candidates.

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

In the U.S. 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, or the ability of our collaborators, 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, or our collaborators, may receive for any approved products.

In the EU, several pieces of legislation recently approved—or still in the process of being approved—will impact regulatory procedures applicable to medicinal products, including those based on genes, tissues, or cells, or Advanced Therapy Medicinal Products. These include, among others, the new Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin intended for human application and the new Regulation (EU) 2021/2282 on health technology assessment, which went into effect on January 12, 2025. Moreover, on April 10, 2024, the European Parliament adopted its position on the European Commission proposal to reform EU pharmaceutical legislation, consisting of a new directive replacing Directive 2001/83/EC and a new regulation replacing Regulation (EC) 726/2004. If approved, this will represent the most significant review of EU pharmaceutical legislation since 2004. The changes proposed are far reaching, including a change in the period of standard regulatory exclusivity, a package of incentives aimed at addressing unmet medical needs, and an extension of the so-called Bolar exemption.

Moreover, it is unclear how regulations and sub-regulatory policy, which fluctuate continually, may affect interpretation and further implementation of the existing law and its practical effects on our business. We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the

cost of healthcare, including drugs and biologics. Any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations. In addition, there is a great degree of uncertainty regarding how recent U.S. Supreme Court decisions, including Loper Bright Enterprises v. Raimondo, 603 U.S. 369 (2024) and Corner Post, Inc. v. Board of Governors of the Federal Reserve System, 603 U.S. 799 (2024), will impact the FDA's enforcement and decision-making authority. Loper Bright explicitly overturned Chevron deference, which previously gave judicial deference to administrative action by agencies in the executive branch. Furthermore, the Supreme Court's decision in Corner Post may result in challenges to FDA decisions by new litigants long into the future.

New federal and state healthcare reform measures may be adopted in the future that may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our pharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved drug. There is also an increasing focus on the price of drugs, both at the state and federal levels, and it is likely that additional pricing controls will be enacted and could harm our business, financial condition and results of operations. For instance, states such as California have begun enacting transparency laws aimed at curbing drug price increases and with the change in administration it is possible that President Trump may issue executive orders with the potential to change a number of prior executive branch actions on drug pricing. We continue to monitor the potential impact of proposals and recently enacted legislation to lower prescription drug costs at the federal and state level. As an example, of changes enacted by a new administration, the Inflation Reduction Act, or the IRA, was signed into law in August 2022 by President Biden, which makes significant changes to how drugs are covered and paid for under the Medicare program, including the creation of financial penalties for drugs whose prices rise faster than the rate of inflation, redesign of the Medicare Part D program to require manufacturers to bear more of the liability for certain drug benefits, and government price-setting for certain Medicare Part D drugs, starting in 2026, and Medicare Part B drugs starting in 2028. We continue to evaluate what effect, if any, the IRA may have on our business. 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 being able to generate revenue, attain profitability or commercialize our products.

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

In addition, there have been a number of other policy, legislative and regulatory proposals aimed at changing the pharmaceutical industry. The U.S. government, state legislatures and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our product candidates from coverage and limit payments for pharmaceuticals. We continue to monitor the potential impact of these and other proposals to lower prescription drug costs at the federal and state level.

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.

We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Any changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

Political uncertainty may have an adverse impact on our operating performance and results of operations, and uncertainty surrounding the potential legal, regulatory, and policy changes by a new U.S. presidential administration may directly affect us and the global economy.*

General political uncertainty may have an adverse impact on our operating performance and results of operations. Changing regulatory policies resulting from the changing political environment could impact our regulatory and compliance costs and future revenues, all of which could materially and adversely affect our business, financial condition, and operating results. Failure to adapt to or comply with evolving regulatory requirements or investor or stakeholder expectations and standards could negatively impact our reputation, ability to do business with certain partners, access to capital, and our stock price. In particular, the U.S. continues to experience significant political events that cast uncertainty on global financial and economic markets, especially following the recent election. The new U.S. administration and recent congressional seat turnover may result in increased regulatory and economic uncertainty. Changes in federal policy by the executive branch and regulatory agencies may occur over time through the new presidential administration's and/or Congress's policy and personnel changes, which could lead to changes involving the level of oversight and focus on the biopharmaceutical industry. However, the nature, timing, and economic and political effects of such potential changes remain highly uncertain. It is presently unclear exactly what actions the new presidential administration in the U.S. will implement, and if implemented, how these actions may impact the biopharmaceutical industry in the U.S. Any actions taken by the new presidential administration may have a negative impact on the U.S. economy and on our business, financial condition, and results of operations.

There is currently significant uncertainty about the future of trade relationships around the world, including potential changes to trade laws and regulations, trade policies, and tariffs. For example, on April 2, 2025, the Administration announced reciprocal tariffs on imported products, which were later paused for 90 days for most countries. In addition, the Administration, through the Department of Commerce, recently announced an investigation of the pharmaceutical industry pursuant to Section 232 of the Trade Expansion Act of 1962, whereby the President may impose tariffs (potentially up to 25%) on the industry if deemed necessary based on national security grounds. Further, the President signed an executive order to reduce prescription drug pricing. The details of each of these proposals are unclear, and the final terms remain uncertain. As a result of these dynamics, we cannot predict the impact to our relationships with third-party manufacturers or our business of any future changes to the U.S.' or other countries' trading relationships or the impact of new laws or regulations adopted by the U.S. or other countries. Evolving international trade relations, new legislation and tariffs may adversely impact our operations and/or financial condition by limiting or preventing the activities of third parties that we engage, increasing import costs or increasing the cost of our operations. New or increased tariffs, export controls or other trade barriers could result in higher prices for the materials we use and the products and product candidates we are developing and could materially impact our supply chain and manufacturing costs.

We are subject to a variety of U.S. and international laws and regulations.

We are currently subject to a number of government laws and regulations, and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect our business, cash flow, results of operations, financial condition, and prospects; these laws and regulations include (i) additional health care reform initiatives in the U.S. or in other countries, including additional mandatory discounts or fees; (ii) the FCPA, FCA or other anti-bribery and corruption laws across all of the jurisdictions that we operate in; (iii) new laws, regulations, and judicial or other governmental decisions affecting pricing, drug reimbursement, and access or marketing within or across jurisdictions; (iv) changes in intellectual property laws; (v) changes in accounting standards; (vi) new and increasing data privacy regulations and enforcement, particularly in the EU, the U.S., and China; (vii) legislative mandates or preferences for local manufacturing of pharmaceutical products; (viii) emerging and new global regulatory requirements for reporting payments and other value transfers to HCPs; (ix) environmental regulations, such as the EU's Corporate Sustainability Reporting Directive; and (x) the potential impact of importation restrictions, embargoes, trade sanctions, and legislative and/or other regulatory changes.

Governments outside the U.S. tend to impose strict price controls, which may adversely affect our revenues, if any.

In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the countries of the EU and the UK, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to undergo a health technology assessment or conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. There can be no assurance that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available, or that

the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing, and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We have adopted a Code of Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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 comply with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our, or our employees', consultants', collaborators', contractors', or vendors' business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, compliance agreements, withdrawal of product approvals, and curtailment of our operations, among other things, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Risks Related to Our Intellectual Property

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

Competitors may infringe the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may be enjoined from manufacturing, use, and marketing our products, or may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO, and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse

can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial. Some of our competitors may be better able to sustain the costs of complex patent litigation because they have substantially greater resources. If there is litigation against us, we may not be able to continue our operations.

Should third parties file patent applications or be issued patents claiming technology also used or claimed by us, we may be required to participate in interference proceedings in the USPTO to determine priority of invention. We may be required to participate in interference proceedings involving our issued patents and pending applications. We may be required to cease using the technology or to license rights from prevailing third parties as a result of an unfavorable outcome in an interference proceeding. A prevailing party in that case may not offer us a license on commercially acceptable terms.

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

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). For example, on November 24, 2021, an opposition proceeding was initiated in the European Patent Office against our European Patent No. 3601533 B1. This opposition proceeding, or any similar proceedings that may arise in the U.S. or foreign jurisdictions, could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant or 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 our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

If we are unable to protect our proprietary rights, we may not be able to compete effectively or operate profitably.

Our success is dependent in part on maintaining and enforcing the patents and other proprietary rights that we have licensed and may develop, and on our ability to avoid infringing the proprietary rights of others. Certain of our intellectual property rights are licensed from another entity, and as such the preparation and prosecution of these patents and patent applications was not performed by us or under our control. Furthermore, patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and, consequently, patent positions in our industry may not be as strong as in other more well-established fields. The patent positions of biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date.

The issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be given to the patents we own or have licensed from the NIH, Cellectis or Novartis if any of these parties, or we, attempt to enforce the patents and/or if they are challenged in court or in other proceedings, such as oppositions, which may be brought in foreign jurisdictions to challenge the validity of a patent. A third party may challenge the validity or enforceability of a patent after its issuance by the Patent Office. It is possible that a competitor may successfully challenge our patents or that a challenge will result in limiting their coverage. Moreover, the cost of litigation to uphold the validity of patents and to prevent infringement can be substantial. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us.

Moreover, it is possible that competitors may infringe our patents or successfully avoid the patented technology through design innovation. To stop these activities, we may need to file a lawsuit. These lawsuits are expensive and would consume time and other resources, even if we were successful in stopping the violation of our patent rights. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of our patents were upheld, a court would refuse to stop the other party on the grounds that its activities are not covered by, that is, do not infringe, our patents.

Should third parties file patent applications, or be issued patents claiming technology also used or claimed by our licensor(s) or by us in any future patent application, we may be required to participate in interference proceedings in the USPTO to determine priority of invention for those patents or patent applications that are subject to the first-to-invent law in the U.S., or may be required to participate in derivation proceedings in the USPTO for those patents or patent applications that are subject to the first-inventor-to-file law in the U.S. We may be required to participate in such interference or derivation proceedings involving our issued patents and pending applications. We may be required to cease using the technology or to license rights from prevailing third parties as a result of an unfavorable outcome in an interference proceeding or derivation proceeding. A prevailing party in that case may not offer us a license on commercially acceptable terms.

We cannot prevent other companies from licensing most of the same intellectual properties that we have licensed or from otherwise duplicating our business model and operations.

Certain intellectual properties that we are using to develop TIL-based cancer therapy products were licensed to us by the NIH. The issued or pending patents that the NIH licensed to us are exclusive and specific with respect to melanoma, breast, HPV-associated, bladder, and lung cancers. No assurance can be given that the NIH has not previously licensed, or that the NIH hereafter will not license to other biotechnology companies some or all of the non-exclusive technologies available to us under the NIH License Agreement. In addition, one U.S. patent in the NIH License Agreement is not owned solely by the NIH. No assurance can be given that NIH's co-owner of the certain U.S. patent in the NIH License Agreement has not previously licensed, or that the co-owner thereafter will not license, to other biotechnology companies some or all of the technologies available to us. Co-ownership of these intellectual properties will create issues with respect to our ability to enforce the intellectual property rights in courts and will create issues with respect to the accountability of one entity with respect to the other.

Since the NCI and numerous other academic institutions already use TIL cell therapy for the treatment of metastatic melanoma and other indications, their methods and data are also available to third parties, who may want to enter into our line of business and compete against us. Other than the Gen 2 manufacturing process, our licensed rights, and our method of use rights in certain indications, we currently do not own any exclusive rights on our entire product portfolio that could be used to fully prevent third parties from duplicating our business plan or from otherwise directly competing against us. While additional technologies that may be developed under our CRADA may be licensed to us on an exclusive basis, no assurance can be given that our existing exclusive rights will be sufficient to prevent others from competing with us and developing substantially similar products.

The use of our technologies could potentially conflict with the rights of others.

Our potential competitors or others may have or acquire patent rights that they could enforce against us. If they do so, then we may be required to alter our products, pay licensing fees or cease activities. If our products conflict with patent rights of others, third parties could bring legal actions against us or our collaborators, licensees, suppliers or customers, claiming damages and seeking to enjoin manufacturing, use and marketing of the affected products. If these legal actions are successful, in addition to any potential liability for damages (including treble damages and attorneys' fees for willful infringement), we could be required to obtain a license to continue manufacturing, promoting the use or marketing the affected products. We may not prevail in any legal action and a required license under the patent may not be available on acceptable terms or at all.

We have conducted extensive freedom-to-operate, or FTO, analyses of the patent landscape with respect to our lead product candidates. Although we continue to undertake FTO analyses of our manufacturing processes, our lead TIL products, and contemplated future processes and products, because patent applications do not publish for 18 months, and because the claims of patent applications can change over time, no FTO analysis can be considered exhaustive. Furthermore, patent and other intellectual property rights in biotechnology remains an evolving area with many risks and uncertainties. As such, we may not be able to ensure that we can market our product candidates without conflict with the rights of others.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other cell therapy and biopharmaceutical companies, our success is 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. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, 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. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

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

We have limited intellectual property rights outside the U.S. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties and our employees and contractors. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against or pursue these claims. For example, we are currently engaged in litigation involving counterclaims that we have brought relating to theft of certain of our trade secrets, breach of confidentiality, and related counterclaims. Even if we are successful in resolving these claims, litigation could result in substantial costs and be a distraction to our management and employees.

Risks Related to Our Securities

Our officers, directors and principal stockholders own a substantial percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our officers, directors, and principal stockholders currently beneficially own a substantial portion of our outstanding voting stock. Therefore, these stockholders have the ability and may continue to have the ability to influence our corporate decision making.

Given current ownership levels, these stockholders may be able to determine some or all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control or influence elections of directors, amendments to our certificate of incorporation or bylaws, or approval of any merger, sale of assets, or other major corporate transaction. This level of control may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Our stock price may be volatile, and our stockholders' investment in our stock could decline in value.

The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including but not limited to:

- volatility and instability in the capital markets due to potential health epidemics and pandemics;
- announcements of the results of clinical trials by us, our collaborators, or our competitors, or negative developments with respect to similar products, including those being developed by our collaborators;
- developments with respect to patents or proprietary rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by equities research analysts and whether our earnings meet or exceed such estimates;
- conditions and trends in the pharmaceutical, biotechnology and other industries;
- receipt, or lack of receipt, of funding in support of conducing our business;
- regulatory developments within, and outside of, the U.S.;
- litigation or arbitration;
- general volatility in the financial markets;
- general economic, political and market conditions and other factors; and
- the occurrence of any of the risks described in this Quarterly Report on Form 10-Q.

You may experience future dilution as a result of future equity offerings or other equity issuances.

We may have to raise additional capital in the future. To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may be lower than the current price per share of our common stock. In addition, investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in prior offerings. Any such issuance could result in substantial dilution to our existing stockholders.

Future sales of our common stock in the public market could cause our stock price to fall.

Our stock price could decline as a result of sales of a large number of shares of our common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

As of March 31, 2025 we had 333,934,387 shares of common stock outstanding. In addition, we had 33,355,625 shares of common stock equivalents that would increase the number of common stock outstanding if these instruments were exercised or converted to purchase common stock based on vesting requirements of stock options and common stock issuable through purchases of employee stock purchase plan, or upon the conversion of preferred stock. The issuance and subsequent sale of the shares underlying these common stock equivalents could depress the trading price of our common stock. On June 10, 2019, our certificate of incorporation was amended to increase the number of authorized shares of our common stock, from 150,000,000 shares to 300,000,000 shares, which was approved by our stockholders on that date. On June 16, 2023, our certificate of incorporation was amended to increase the number of authorized shares of our common stock from 300,000,000 to 500,000,000 shares, which amendment was approved by our stockholders on June 6, 2023.

In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. For example, in February 2024, we issued 23,014,000 shares of common stock in connection with an underwritten public offering, and we may offer

additional shares under our automatic shelf registration statement in the future. Future issuances may result in substantial dilution to our existing stockholders and could cause our stock price to decline.

If equities or industry analysts do not publish research or reports about our company, or if they issue adverse or misleading opinions regarding us or our stock, our stock price and trading volume could decline.

Although we have research coverage by equities analysts, if coverage is not maintained, the market price for our stock may be adversely affected. Our stock price also may decline if any analyst who covers us issues an adverse or erroneous opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet analysts' expectations. If one or more analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline and possibly adversely affect our ability to engage in future financings.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results. As a result, we could become subject to sanctions or investigations by regulatory authorities and/or stockholder litigation, which could harm our business and have an adverse effect on our stock price.

As a public reporting company, we are subject to various regulatory requirements, including the Sarbanes-Oxley Act of 2002, which requires our management to assess and report on our internal controls over financial reporting. Nevertheless, in future years, our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls that we would be required to remediate in a timely manner to be able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act each year. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act each year, we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities which would require additional financial and management resources and could adversely affect the market price of our common stock. In addition, material weaknesses in our internal controls could result in a loss of investor confidence in our financial reports.

We are, and in the future may be, subject to federal or state securities or related legal actions that could adversely affect our results of operations and our business.

Federal and state securities and related legal actions may result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business or affect our reputation. We may not be successful in defending future claims and cannot provide assurance that insurance proceeds will be sufficient to cover any costs or liability under such claims.

For example, on December 11, 2020, a purported stockholder derivative complaint was filed by plaintiff Leo Shumacher against us, as nominal defendant, and then current directors, as defendants, in the Court of Chancery in the State of Delaware, or the Court. The complaint alleges breach of fiduciary duty and a claim for unjust enrichment in connection with alleged excessive compensation of certain of our non-executive directors and seeks unspecified damages on behalf of our company. The parties agreed to proposed settlements in 2022 and 2024, which the Court declined to approve. The Company continues to vigorously defend against the complaint. The outcome of this and other future litigation is uncertain.

Our Board of Directors could issue one or more additional series of preferred stock without stockholder approval with the effect of diluting existing stockholders and impairing their voting and other rights.

Our certificate of incorporation, as amended, authorizes the issuance of up to 50,000,000 shares of "blank check" preferred stock (of which only 17,000 shares were issued as Series A Convertible Preferred Stock and 11,500,000 shares were issued as Series B Convertible Preferred Stock) with designations, rights, and preferences as may be determined from time to time by our Board of Directors. Our Board of Directors is empowered, without stockholder approval, to issue one or more series of preferred stock with dividend, liquidation, conversion, voting, or other rights which could dilute the interest of, or impair the voting power of, our common stockholders. The issuance of a series of preferred stock could be used as a method of discouraging, delaying, or preventing a change in control. For example, it would be possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change in control of our company.

We do not anticipate paying cash dividends for the foreseeable future, and therefore investors should not buy our stock if they wish to receive cash dividends.

We have never declared or paid any cash dividends or distributions on our common stock. We currently intend to retain our future earnings to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation, as amended, and amended and restated bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our Board of Directors has the authority to issue up to 38,483,000 additional shares of preferred stock and to fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. 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 certificate of incorporation, as amended, designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation, as amended, provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, creditors or other constituents, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation, as amended, or our amended and restated bylaws, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. This choice of 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 such lawsuits against us and our directors, officers, and employees. Further, this choice of forum provision does not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Securities Act or any other claim for which the federal and state courts have concurrent jurisdiction. Accordingly, our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

If a court were to find these provisions of our certificate of incorporation, as amended inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, results of operations and financial condition. Even if we are

successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

Provisions in our amended and restated bylaws 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 bylaws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. shall be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act. This provision limits the ability of our shareholders to bring claims under the Securities Act in any court other than the U.S. federal courts, which ultimately may disadvantage our shareholders or be cost prohibitive. Notwithstanding the foregoing, there is uncertainty as to whether a court (other than those states which have upheld the validity of such a provision) would enforce such a provision and whether investors can waive compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the exclusive forum provision only applies to claims brought under the Securities Act and does not apply to actions arising under the Exchange Act, which is already subject to federal courts as the exclusive forum.

If a court were to find these provisions of our amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, results of operations and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

Item 2. Unregistered Sales of Securities, Use of Proceeds, and Issuer Purchases of Equity Securities.

Nothing to report.

Item 3. Defaults Upon Senior Securities.

Nothing to report.

Item 4. Mine Safety Disclosures

Nothing to report.

Item 5. Other Information.

During the first quarter of 2025, none of our directors or executive officers adopted or terminated a Rule 10b5-1 trading arrangement (as defined in Item 408(a)(1)(i) of Regulation S-K) or adopted or terminated a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) for the purchase or sale of securities of the Company, whether or not intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act.

During the first quarter of 2025, the Company did not adopt or terminate a Rule 10b5-1 trading arrangement (as defined in Item 408(a)(1)(i) of Regulation S-K) for the purchase or sale of securities of the Company, whether or not intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit	Description
3.1	Certificate of Incorporation, as amended, of Registrant (incorporated herein by reference to Exhibit 3.1 to Registrant's Current Report on Form 8-K filed with the Commission on July 10, 2023).
3.2	Fourth Amended and Restated Bylaws of Iovance Biotherapeutics, Inc. (incorporated herein by reference to Exhibit 3.1 to Registrant's Current Report on Form 8-K filed with the Commission on March 29, 2024).
31.1++	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
31.2++	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.
32.1++	Section 1350 Certification of Chief Executive Officer (furnished herewith).
32.2++	Section 1350 Certification of Chief Financial Officer (furnished herewith).
101.INS++	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).
101.SCH++	Inline XBRL Taxonomy Schema Linkbase Document.
101.CAL++	Inline XBRL Taxonomy Calculation Linkbase Document.
101.DEF++	Inline XBRL Taxonomy Definition Linkbase Document.
101.LAB++	Inline XBRL Taxonomy Labels Linkbase Document.
101.PRE++	Inline XBRL Taxonomy Presentation Linkbase Document.
104	Cover Page Interactive Data File (the cover page interactive date file does not appear in the Interactive Date File because its XBRL tags are embedded within the Inline XBRL document).

++ Filed herewith (unless otherwise noted as being furnished herewith).
# Indicates a management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Iovance Biotherapeutics, Inc.

May 8, 2025

By: /s/ Frederick G. Vogt, Ph.D., J.D.
Frederick G. Vogt, Ph.D., J.D.
Interim Chief Executive Officer and President, and General Counsel (Principal Executive Officer)

May 8, 2025

By: /s/ Jean-Marc Bellemin
Jean-Marc Bellemin
Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION

I, Frederick G. Vogt, PhD., J.D, Interim Chief Executive Officer and President, and General Counsel of Iovance Biotherapeutics, Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Iovance Biotherapeutics, Inc.;

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

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

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my 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 my 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 my 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my 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.

Dated: May 8, 2025

By: /s/ Frederick G. Vogt, PhD., J.D.
Frederick G. Vogt, PhD., J.D.
Interim Chief Executive Officer and President, and General Counsel (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Jean-Marc Bellemin, Chief Financial Officer of Iovance Biotherapeutics, Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Iovance Biotherapeutics, Inc.;

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

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

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my 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 my 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 my 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my 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.

Dated: May 8, 2025

By: /s/ Jean-Marc Bellemin
Jean-Marc Bellemin
Chief Financial Officer
(Principal Financial Officer & Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Iovance Biotherapeutics, Inc. (the "Company") for the quarter ended March 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Frederick G. Vogt, PhD., J.D., Interim Chief Executive Officer and President, and General Counsel, hereby certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: May 8, 2025

By: /s/ Frederick G. Vogt, PhD., J.D.
Frederick G. Vogt, PhD., J.D.
Interim Chief Executive Officer and President, and General Counsel (Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Iovance Biotherapeutics, Inc. (the "Company") for the quarter ended March 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Jean-Marc Bellemin, Chief Financial Officer, hereby certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: May 8, 2025

By: /s/ Jean-Marc Bellemin
Jean-Marc Bellemin
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.