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 **June 30, 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 August 1, 2025, the issuer had 361,853,896 shares of common stock, par value $0.000041666 per share, outstanding.

IOVANCE BIOTHERAPEUTICS, INC.
FORM 10-Q
For the Quarter Ended June 30,2025

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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 timing, execution and expected benefits of our restructuring plan announced in August 2025;
- 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)

	June 30, 2025	December 31, 2024
ASSETS		
Current Assets		
Cash and cash equivalents	$ 132,469	$ 115,694
Trade accounts receivable	59,938	69,340
Short-term investments	168,714	208,087
Inventory	49,833	51,520
Prepaid expenses and other assets	11,546	12,377
Total Current Assets	422,500	457,018
Property and equipment, net	122,473	109,081
Intangible assets, net	296,253	282,398
Operating lease right-of-use assets	49,949	55,201
Restricted cash	5,944	6,359
Long-term assets	10,318	369
Total Assets	$ 907,437	$ 910,426
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 32,004	$ 27,509
Accrued expenses and other liabilities	89,081	81,936
Note payable - current	1,000	—
Operating lease liabilities	7,070	12,896
Total Current Liabilities	129,155	122,341
Non-Current Liabilities		
Operating lease liabilities – non-current	45,096	44,365
Deferred tax liabilities	34,698	32,315
Long-term note payable	—	1,000
Total Non-Current Liabilities	79,794	77,680
Total Liabilities	208,949	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 June 30, 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 June 30, 2025 and December 31, 2024 respectively	2	3
Common stock, $0.000041666 par value; 500,000,000 shares authorized, 341,919,364 and 305,252,194 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	14	13
Accumulated other comprehensive loss (income)	20,859	(1,046)
Additional paid-in capital	3,289,986	3,095,987
Accumulated deficit	(2,612,373)	(2,384,552)
Total Stockholders' Equity	698,488	710,405
Total Liabilities and Stockholders' Equity	$ 907,437	$ 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue				
Product revenue	$ 59,952	$ 31,106	$ 109,276	$ 31,821
Total revenue	59,952	31,106	109,276	31,821
Costs and expenses				
Cost of sales	$ 56,664	$ 31,368	$ 106,405	$ 38,629
Research and development	79,363	62,084	156,242	141,867
Selling, general, and administrative	37,699	39,568	81,624	70,961
Total costs and expenses	173,726	133,020	344,271	251,457
Loss from operations	(113,774)	(101,914)	(234,995)	(219,636)
Other income				
Interest and other income, net	4,104	3,355	7,324	6,693
Net Loss before income taxes	$ (109,670)	$ (98,559)	$ (227,671)	$ (212,943)
Income tax (expense) benefit	(1,988)	1,458	(150)	2,866
Net Loss	$ (111,658)	$ (97,101)	$ (227,821)	$ (210,077)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.33)	$ (0.34)	$ (0.69)	$ (0.76)
Weighted Average Shares of Common Stock Outstanding, Basic and Diluted	334,511	284,817	328,721	275,518

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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Net Loss	$ (111,658)	$ (97,101)	$ (227,821)	$ (210,077)
Other comprehensive loss:				
Unrealized gain (loss) on investments	(30)	20	(140)	(49)
Foreign currency translation adjustment	14,595	390	22,045	(1,951)
Comprehensive Loss	$ (97,093)	$ (96,691)	$ (205,916)	$ (212,077)

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 June 30, 2025 and 2024
(unaudited; in thousands, except share information)

	Series A Convertible Preferred Sock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance - March 31, 2025	194	$ —	1,932,667	$ 2	333,934,387	$ 14	$3,262,270	$ 6,294	$ (2,500,715)	$ 767,865
Stock-based compensation expense	—	—	—	—	—	—	14,484	—	—	14,484
Common stock issued upon purchase of employee stock purchase plan	—	—	—	—	355,708	—	669	—	—	669
Vesting of restricted shares issued for services	—	—	—	—	583,120	—	—	—	—	—
Tax payments related to shares retired for vested restricted stock units	—	—	—	—	(257,496)	—	(504)	—	—	(504)
Common stock sold in public and/or at the market offering, net of offering costs	—	—	—	—	7,303,645	—	13,067	—	—	13,067
Unrealized loss on investments	—	—	—	—	—	—	—	(30)	—	(30)
Foreign currency cumulative translation adjustment	—	—	—	—	—	—	—	14,595	—	14,595
Net loss	—	—	—	—	—	—	—	—	(111,658)	(111,658)
Balance - June 30, 2025	194	$ —	1,932,667	$ 2	341,919,364	$ 14	$3,289,986	$ 20,859	$ (2,612,373)	$ 698,488
Balance - March 31, 2024	194	$ —	2,842,158	$ 3	279,756,339	$ 12	$2,805,244	$ 116	$ (2,125,351)	$ 680,024
Stock-based compensation expense	—	—	—	—	—	—	31,830	—	—	31,830
Common stock issued upon purchase of employee stock purchase plan	—	—	—	—	294,222	—	1,562	—	—	1,562
Vesting of restricted shares issued for services	—	—	—	—	289,588	—	—	—	—	—
Tax payments related to shares retired for vested restricted stock units	—	—	—	—	(101,140)	—	(1,001)	—	—	(1,001)
Common stock sold in public and/or at the market offerings, net of offering costs	—	—	—	—	17,017,492	—	152,426	—	—	152,426
Common stock issued upon exercise of stock options	—	—	—	—	49,498	—	390	—	—	390
Unrealized gain on investments	—	—	—	—	—	—	—	20	—	20
Foreign currency cumulative translation adjustment	—	—	—	—	—	—	—	390	—	390
Net loss	—	—	—	—	—	—	—	—	(97,101)	(97,101)
Balance - June 30, 2024	194	$ —	2,842,158	$ 3	297,305,999	$ 12	$2,990,451	$ 526	$ (2,222,452)	$ 768,540

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

IOVANCE BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Stockholders' Equity
For the Six Months Ended June 30, 2025 and 2024
(unaudited; in thousands, except share information)

	Series A Convertible Preferred Sock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
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	—	—	—	—	—	—	37,454	—	—	37,454
Common stock issued upon purchase of employee stock purchase plan	—	—	—	—	355,708	—	669	—	—	669
Vesting of restricted shares issued for services	—	—	—	—	4,141,748	—	—	—	—	—
Tax payments related to shares retired for vested restricted stock units	—	—	—	—	(1,645,397)	—	(6,148)	—	—	(6,148)
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	—	—	—	—	32,903,034	1	162,008	—	—	162,009
Common stock issued from preferred stock conversion	—	—	(909,491)	(1)	909,491	—	1			0
Unrealized loss on investments	—	—	—	—	—	—	—	(140)	—	(140)
Foreign currency cumulative translation adjustment	—	—	—	—	—	—	—	22,045		22,045
Net loss	—	—	—	—	—	—	—	—	(227,821)	(227,821)
Balance - June 30, 2025	194	$ —	1,932,667	$ 2	341,919,364	$ 14	$3,289,986	$ 20,859	$ (2,612,373)	$ 698,488
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	—	—	—	—	—	—	49,603	—	—	49,603
Common stock issued upon purchase of employee stock purchase plan	—	—	—	—	294,222	—	1,562	—	—	1,562
Vesting of restricted shares issued for services	—	—	—	—	1,169,830	—		—	—	—
Tax payments related to shares retired for vested restricted stock units	—	—	—	—	(416,511)	—	(5,701)	—	—	(5,701)
Common stock issued upon exercise of stock options	—	—	—	—	91,251	—	754	—	—	754
Common stock sold in public and/or at the market offering, net of offering costs	—	—	—	—	40,031,492	1	349,785	—	—	349,786
Unrealized loss on investments	—	—	—	—	—	—	—	(49)	—	(49)
Foreign currency cumulative translation adjustment	—	—	—	—	—	—	—	(1,951)	—	(1,951)
Net loss	—	—	—	—	—	—	—	—	(210,077)	(210,077)
Balance - June 30, 2024	194	$ —	2,842,158	$ 3	297,305,999	$ 12	$2,990,451	$ 526	$ (2,222,452)	$ 768,540

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)

	Six Months Ended June 30,	
	2025	**2024**
Cash Flows from Operating Activities		
Net loss	$ (227,821)	$ (210,077)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	37,858	47,644
Unrealized foreign exchange loss	(97)	(86)
Amortization of intangible assets	11,104	10,119
Amortization of right of use asset	5,747	4,689
Depreciation and amortization of property and equipment	6,152	5,963
Deferred tax expense	150	(2,866)
Excess and obsolescence reserve	8,311	—
Accretion of discounts and premiums on investments	(4,149)	(4,834)
Loss on asset disposals	44	—
Changes in assets and liabilities:		
Prepaid expenses, other assets and long-term assets	(10,138)	5,677
Trade accounts receivable	9,402	(31,453)
Inventory	(7,028)	(15,594)
Operating lease liabilities	(5,590)	(5,478)
Accounts payable	2,945	(16,205)
Accrued expenses and other liabilities	1,969	(8,207)
Net cash used in operating activities	(171,141)	(220,708)
Cash Flows from Investing Activities		
Maturities of investments	210,000	202,000
Purchase of investments	(166,619)	(216,101)
Cash paid for acquisition, including contingent consideration, net of cash acquired	—	(52,573)
Purchase of property and equipment	(13,672)	(4,613)
Net cash provided by (used) in investing activities	29,709	(71,287)
Cash Flows from Financing Activities		
Tax payments related to shares withheld for vested restricted stock units	(6,148)	(5,701)
Proceeds from the issuance of common stock under employee stock purchase plan	669	1,562
Proceeds from the issuance of common stock upon exercise of options	15	754
Proceeds from the issuance of common stock, net	162,009	349,786
Net cash provided by financing activities	156,545	346,401
Effect of foreign exchange rate changes	1,247	(616)
Net increase in cash, cash equivalents and restricted cash	16,360	53,790
Cash, Cash Equivalents and Restricted Cash Beginning of Period	122,053	181,318
Cash, Cash Equivalents and Restricted Cash End of Period	$ 138,413	$ 235,108
Supplemental disclosure of non-cash investing and financing activities:		
Net unrealized loss on investments	140	(49)
Acquisition of property and equipment included in accounts payable and accrued expenses	13,283	2,342
Intangible asset and deferred tax liability arising from contingent consideration	—	23,495
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	496	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 United Kingdom ("UK"), Canada, Australia, Switzerland, and European Union ("EU"). In June 2024, the Company submitted a centralized marketing authorization application ("MAA") to the European Medicines Agency ("EMA") for lifileucel which was validated and accepted for review by the EMA in August 2024. Following interactions with EMA's Committee for Medicinal Products for Human Use ("CHMP"), Iovance notified EMA of its decision to withdraw the MAA and is working to determine a resubmission strategy. An MAA was submitted to the Medicines and Healthcare Products Regulatory Agency in the UK and is on track for potential approval and launch in the first half of 2026. Australia's Therapeutic Goods Administration granted Priority Review to Amtagvi® with a decision anticipated by early 2026, and the Swiss Medic recommended Priority Review ahead of the Swiss regulatory submission planned in the fourth quarter of 2025. A new drug submission ("NDS") was deemed eligible for Notice of Compliance with Conditions ("NOC/c") by Health Canada and submitted in 2024 and approval is expected in the third quarter of 2025, which would make lifileucel the first and only approved therapy in this treatment setting in Canada. 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 and six months ended June 30, 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 June 30, 2025, the Company had $307.1 million in cash, cash equivalents, short-term investments, and restricted cash ($132.5 million of cash and cash equivalents, $168.7 million in short-term investments, and $5.9 million in restricted cash). The Company has 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 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 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 $227.8 million for the six months ended June 30, 2025 and used $171.1 million of cash in its operating activities during the six months ended June 30, 2025.

The Company expects to continue to incur significant expenses to support its ongoing 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 and six months ended June 30, 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 June 30, 2025 and December 31, 2024, restricted cash totaled $5.9 million and $6.4 million, respectively. 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 June 30, 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. 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 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):

	June 30,	
	2025	2024
Cash and cash equivalents	$ 132,469	$ 228,678
Restricted cash	5,944	6,430
Total cash, cash equivalents and restricted cash	$ 138,413	$ 235,108

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 June 30, 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 do 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 June 30, 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 and manufacturing 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 and six month period ended June 30, 2025 and during the period from approval through June 30, 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 June 30, 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 June 30, 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 June 30, 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:

	June 30,	
	2025	**2024**
Stock options	18,994,381	18,880,137
Restricted stock units	11,411,549	11,838,116
Employee Stock Purchase Plan	570,824	250,400
Series A Convertible Preferred Stock*	97,000	97,000
Series B Convertible Preferred Stock*	1,932,667	2,842,158
	33,006,421	33,907,811

** 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, 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 June 30, 2025 and December 31, 2024 were as follows (in thousands):

As of June 30, 2025	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 168,738	$ —	$ (24)	$ 168,714
Money market funds	81,369	—	—	81,369
Total investments	$ 250,107	$ —	$ (24)	$ 250,083

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 June 30, 2025 and December 31, 2024, are classified as follows in the Company's condensed consolidated balance sheets (in thousands):

Classified as:	June 30, 2025	December 31, 2024
Cash equivalents	$ 81,369	$ 61,432
Short-term investments	168,714	208,087
Total investments	$ 250,083	$ 269,519

Cash equivalents in the tables above exclude cash demand deposits of $51.1 million and $54.3 million as of June 30, 2025 and December 31, 2024, respectively. Unrealized gains and losses are included in accumulated other comprehensive loss, and as of June 30, 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 June 30, 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 June 30, 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 June 30, 2025			
	Level 1	Level 2	Level 3	Total
U.S. treasury securities	$ 168,714	$ —	$ —	$ 168,714
Money market funds	81,369	—	—	81,369
Total investments	$ 250,083	$ —	$ —	$ 250,083

	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 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.

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 June 30, 2025 and December 31, 2024, are as follows (in thousands):

	June 30, 2025	December 31, 2024
Developed technology	$ 332,717	$ 304,939
Assembled workforce	701	643
Intellectual property license	7,500	7,500
Patents	475	—
Total intangible assets	$ 341,393	$ 313,082
Less: accumulated amortization	(45,140)	(30,684)
Intangible assets, net	$ 296,253	$ 282,398

The Company recognized amortization expense of $5.7 million and $11.1 million during the three and six months ended June 30, 2025, and $5.5 million and $10.1 million during the three and six months ended June 30, 2024, respectively. 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 and six months ended June 30, 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 $11.7 million, $23.3 million, $23.2million, $23.2 million, and $23.2 million, respectively.

NOTE 6. INVENTORY

As of June 30, 2025 and December 31, 2024, inventory consists of the following (in thousands):

	June 30, 2025	December 31, 2024
Raw materials	$ 34,487	$ 27,743
Work in process	10,181	8,765
Finished goods	14,941	15,012
Total inventory	$ 59,609	$ 51,520

Inventory recorded as of June 30, 2025 is net of $8.3 million for excess and obsolescence reserves recorded for the three and six months ended June 30, 2025, such reserve being primarily related to excess Proleukin® inventory resulting from a manufacturer contract inherited in the Acquisition for which we cannot yet fully utilize the required purchase quantities while we scale the Amtagvi® commercial launch.

Inventory expected to be used or sold more than twelve months from the balance sheet date is classified as long-term other assets on the condensed consolidated balance sheet. As of June 30, 2025 the Company recorded $9.8 million of inventory as long-term other assets. There was no long-term inventory recorded as of December 31, 2024.

NOTE 7. REVENUE

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Amtagvi®	$ 54,074	$ 12,819	$ 97,645	$ 12,819
Proleukin®	5,878	18,287	11,631	19,002
Total net revenue	$ 59,952	$ 31,106	$ 109,276	$ 31,821

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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Gross revenue	$ 60,866	$ 32,633	$ 110,519	$ 33,352
GTN adjustments:				
Government rebates and chargebacks	(152)	(51)	(297)	(51)
Wholesaler fees and cash discounts	(618)	(931)	(787)	(935)
Other rebates, returns, discounts and adjustments	(144)	(545)	(159)	(545)
Total GTN adjustments	(914)	(1,527)	(1,243)	(1,531)
Net revenue	$ 59,952	$ 31,106	$ 109,276	$ 31,821

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
United States	$ 58,605	$ 30,034	$ 107,125	$ 30,034
Rest of world	1,347	1,072	2,151	1,787
Net revenue	$ 59,952	$ 31,106	$ 109,276	$ 31,821

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 and six months ended June 30, 2025 and 2024, respectively (in thousands, except percentages):

	Three Months Ended June 30, 2025		Six Months Ended June 30, 2025	
	$	%	$	%
Customer A	$ 6,556	11%	$ *	0%
Other customers	54,310	89%	110,519	100%
Gross revenue	$ 60,866	100%	$ 110,519	100%
GTN adjustments	(914)		(1,243)	
Net revenue	$ 59,952		$ 109,276	

** Represents customer below 10%*

	Three Months Ended June 30, 2024		Six Months Ended June 30, 2024	
	$	%	$	%
Customer A	$ 12,213	37%	$ 12,213	37%
Customer B	4,441	14%	4,441	13%
Other customers	15,979	49%	16,698	50%
Gross revenue	$ 32,633	100%	$ 33,352	100%
GTN adjustments	(1,527)		(1,531)	
Net revenue	$ 31,106		$ 31,821	

NOTE 8. PROPERTY AND EQUIPMENT, NET

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

	June 30, 2025	December 31, 2024
Leasehold improvements	$ 85,901	$ 67,375
Lab, process, and validation equipment	25,935	25,477
Utility equipment	7,306	5,990
Office furniture and equipment	1,997	1,998
Computer software	8,512	8,512
Computer equipment	2,135	448
Machinery and equipment	504	363
Construction in progress	32,288	34,938
Total property and equipment, cost	$ 164,578	$ 145,101
Less: Accumulated depreciation and amortization	(42,105)	(36,020)
Property and equipment, net	$ 122,473	$ 109,081

Depreciation and amortization expense for the three and six months ended June 30, 2025 was $3.4 million and $6.2 million, respectively. Depreciation and amortization expense for the three and six months ended June 30, 2024 was $3.0 million and $6.0 million, respectively.

NOTE 9. ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	June 30, 2025	December 31, 2024
Accrued payroll and employee related expenses	$ 24,299	$ 31,910
Clinical related	22,491	13,017
Manufacturing related	15,025	10,084
Facilities related	11,031	6,748
Legal and related services	2,035	2,466
Inventory and distribution related	7,973	12,471
Other accrued expenses	6,227	5,240
Total accrued expenses	$ 89,081	$ 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 June 30, 2025, 341,919,364 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.

For the six months ended June 30, 2025, the Company raised approximately $162.0 million in net proceeds, through the sale of 32,903,034 shares of common stock pursuant to the 2023 Sale Agreement at a weighted average price per share of $5.02. For the six months ended June 30, 2024, the Company raised approximately $152.4 million in net proceeds, after offering costs, through the sale of 17,017,492 shares of common stock pursuant to the 2023 Sale Agreement at a weighted average price per share of $8.41.

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 June 30, 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 six months ended June 30, 2025 and 2024, no shares of Series A Convertible Preferred Stock were converted into shares of common stock. As of June 30, 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 six months ended June 30, 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 six months ended June 30, 2024. As of June 30, 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. On June 10, 2025, 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 36,700,000 to 49,200,000 shares and permit share recapture from the 2014 Plan, which became effective immediately. As of June 30, 2025, 3,833,925 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 June 30, 2025, 50,109 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 June 30, 2025 and the changes during the six months ended June 30, 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	1,797,270	3.63		
Exercised	(2,586)	5.80		
Expired/Cancelled	(1,018,429)	17.74		
Outstanding at June 30, 2025	18,994,381	$ 16.09	5.99	$ —
Ending vested and expected to vest at June 30, 2025	18,994,381	$ 16.09	5.99	$ —
Options exercisable at June 30, 2025	14,700,758	$ 18.90	5.11	$ —

As of June 30, 2025, there was $16.7 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 1.97 years as of June 30, 2025. The weighted average grant date fair value for employee options granted under the Company's stock option plans during the six months ended June 30, 2025 was $2.61 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 June 30, 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 June 30, 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. On June 10, 2025, 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 1,900,000 to 2,900,000 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 and six months ended June 30, 2025 was $0.3 million, and $0.7 million, respectively. The compensation expense related to the 2020 ESPP for the three and six months ended June 30, 2024 was $0.3 million, and $0.7 million, respectively. As of June 30, 2025, there was $0.6 million of unrecognized compensation cost associated with the 2020 ESPP, which is expected to be recognized over the remaining 5.4 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 June 30, 2025 and the changes during the six months ended June 30, 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	6,919,396	3.99
Vested/Released	(4,141,748)	16.08
Canceled/Forfeited	(913,742)	9.64
Outstanding at June 30, 2025	11,411,549	$ 8.43
Ending vested and expected to vest at June 30, 2025	11,115,730	$ 8.43

As of June 30, 2025, there was $73.8 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 2.19 years. The aggregate intrinsic value of the unvested RSUs and PRSUs outstanding as of June 30, 2025 was $19.6 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Cost of sales	$ 2,149	$ 2,297	$ 4,569	$ 2,297
Research and development	6,359	13,107	16,276	22,022
Selling, general, and administrative	6,435	15,062	17,013	23,325
Total stock-based compensation expense	$ 14,943	$ 30,466	$ 37,858	$ 47,644

The amount included in capitalized inventory for stock-based compensation expense for personnel engaged with manufacturing activities was $0.8 million as of June 30, 2025, and $1.2 million as of December 31, 2024.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Stock option expense	$ 3,485	$ 5,267	$ 7,278	$ 11,030
Restricted stock expense	11,128	24,876	29,880	35,943
ESPP expense	330	323	700	671
Total stock-based compensation expense	$ 14,943	$ 30,466	$ 37,858	$ 47,644

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 and six months ended June 30, 2025 and 2024.

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2025	2024	2025	2024
Net sales	$ 59,952	$ 31,106	$ 109,276	$ 31,821
Direct cost of goods sold (a)	$ 49,798	$ 21,726	$ 92,861	$ 24,407
Acquisition related cost of sales (b)	$ 5,637	$ 5,432	$ 10,989	$ 10,012
Royalties	$ 1,229	$ 4,210	$ 2,555	$ 4,210
Total cost of sales	$ 56,664	$ 31,368	$ 106,405	$ 38,629
Expenses				
Research and development	$ 71,314	$ 45,448	$ 135,802	$ 115,734
General and administrative	$ 21,275	$ 17,600	$ 43,532	$ 35,562
Sales and marketing	$ 9,990	$ 6,774	$ 21,080	$ 11,929
Other segment items (c)	$ 12,367	$ 27,017	$ 30,278	$ 40,044
Total expenses	$ 114,946	$ 96,839	$ 230,692	$ 203,269
Net loss	$ (111,658)	$ (97,101)	$ (227,821)	$ (210,077)

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 and the evaluation in clinical trials of strategies for development of more potent TILs.

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 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 is required to make quarterly payments 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 $0.8 million and $1.7 million, for the three and six months ended June 30, 2025 and $0.5 million and $1.0 million for the three and six months ended June 30, 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. The Company recorded $0.2 million and $0.4 million, for the three and six months ended June 30, 2025, and $0.2 million and $0.3 million for the three and six months ended June 30, 2024, 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 a de minimis amount and $0.1 million, for the three and six months ended June 30, 2025, respectively, and $0.1 million for each of the three and six months ended June 30, 2024, respectively, as a research and development costs.

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. There was no activity for the three and six months ended June 30, 2025 under this agreement. For the three months ended June 30, 2024, the Company recorded a de minimis cost as a research and development cost, and a benefit of $0.4 million for the six months ended June 30, 2024 as a result of finalization of the cost reconciliation.

Minaris Advanced Therapies

In November 2016, the Company entered into a manufacturing services agreement (the "First 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 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 MSA expired in November 2022.

In October 2022, Iovance Manufacturing LLC entered into an additional three-year manufacturing and services agreement (the "Second MSA") with WuXi Advance Therapies, Inc. and its parent company, WuXi Apptec Co., Ltd (collectively, "WuXi"), which, following the acquisition of WuXi, was amended in May 2025 to replace WuXi as party to the Second MSA with Advanced Therapies, LLC (operating under a trade name of Minaris Advanced Therapies, or "Minaris"). Under the Second MSA, Iovance Manufacturing LLC entered into a statement of work for two cGMP manufacturing suites to be operated by Minaris for Iovance Manufacturing LLC to support clinical and commercial manufacturing and related testing services. The Second MSA and its related statement of work superseded the statements of work under the First 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 Minaris of $6.1 million and $3.8 million for the three months ended June 30, 2025 and 2024, respectively, and $14.5 million and $9.6 million for the six months ended June 30, 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 and $0.2 million for each of the three and six months ended June 30, 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 zero and $2.5 million related to the initiation of patient dosing for the three and six months ended June 30, 2025. No expenses were recorded for the three and six months ended June 30, 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 and six months ended June 30, 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 $8.2 million, $9.1 million, and $8.2 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):

	June 30, 2025	December 31, 2024
Operating lease right-of-use assets	$ 49,949	$ 55,201
Operating lease liabilities		
Current portion included in current liabilities	$ 7,070	$ 12,896
Long-term portion included in non-current liabilities	45,096	44,365
Total operating lease liabilities	$ 52,166	$ 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating lease cost	$ 3,925	$ 3,996	$ 7,893	$ 7,793
Variable lease cost	639	1,102	1,582	2,710
Short-term lease cost	79	132	183	188
Total lease cost	$ 4,643	$ 5,230	$ 9,658	$ 10,691
Other information				
Cash paid for amounts included in the measurement of lease liabilities included in cash flows from operations	$ 3,620	$ 4,291	$ 7,830	$ 8,581
Increase(Decrease) in right-of-use assets from lease modifications	$ 1,925	$ —	$ 496	$ 11,297
Weighted-average remaining lease terms (years)			13.59	11.73
Weighted-average discount rates			7.7 %	7.7 %

As of June 30, 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	$ 2,996	$ 4,728	$ 7,724
2026	5,985	—	5,985
2027	4,858	—	4,858
2028	4,964	—	4,964
2029	4,838	—	4,838
Thereafter	58,004	—	58,004
Total lease payments	$ 81,645	$ 4,728	$ 86,373
Less: Present value adjustment	(34,054)	(153)	(34,207)
Operating lease liabilities	$ 47,591	$ 4,575	$ 52,166

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. On May 29, 2025, the Court issued an order consolidating the cases and appointing the Paul Berger Revocable Trust as lead plaintiff and its counsel as lead counsel. The Company intends to vigorously defend against this matter.

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, which the Solomon Plaintiffs opposed.

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 was 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) did not have an opening brief on file, which the Second Circuit Court denied, and (b) had 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 would 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.

Securities Class Actions and Shareholder Derivative Cases. On May 15, 2025, two putative securities class actions were filed in the United States District Court for the Northern District of California, captioned *Sundaram v. Iovance Biotherapeutics, Inc., et al*., No. 25-cv-04177 ("*Sundaram*") and *Farberov v. Iovance Biotherapeutics, Inc., et al*., No. 25-cv-04199 ("*Farberov*"), naming the Company and certain of the Company's officers as defendants. The complaints purport to assert claims against the defendants under Section 10(b) of the Securities Exchange Act of 1934 (the "1934 Act"), SEC Rule 10b-5, and Section 20(a) of the 1934 Act. The *Sundaram* action is on behalf of persons or entities who acquired the Company's common stock between August 8, 2024 and May 8, 2025, and the *Farberov* action is on behalf of persons or entities who acquired the Company's common stock between May 9, 2024 and May 8, 2025. Each putative class action arises out of the Company's quarterly disclosure of financial results on May 8, 2025, and the decline in the price of the Company's common stock the following day, and involve allegations that during the respective class periods, defendants made materially false and misleading statements regarding the Company's expected revenue for fiscal year 2025, which the plaintiffs claim artificially inflated the price of the Company's common stock. The actions seek compensatory damages and costs and expenses incurred in the actions, including attorneys' fees.

On June 5, 2025, two putative shareholder derivative lawsuits were filed in the United States District Court for the Northern District of California, captioned *Hollin v. Vogt, et al*., 3:25-cv-04740 and *Gera, et al. v. Vogt, et al*., 3:25-cv-04794, purportedly brought on behalf of Iovance against certain current and former officers and directors of the Company. Iovance is named as a nominal defendant in the complaints. The lawsuits contain allegations based on or similar to those in the putative securities class actions and claim, among other things, that the named individual defendants breached their fiduciary duties and violated Section 14(a) of the 1934 Act by issuing or causing the Company to issue false and misleading disclosures concerning the Company's financial forecasts for fiscal year 2025. Before filing the complaints, the plaintiffs did not make a demand that the Company's Board of Directors consider the claims therein. The lawsuits seek money damages, corporate governance reforms, restitution, punitive damages, and costs and expenses of the lawsuits, including attorneys' fees.

Based on the preliminary nature of the proceedings in these actions, the outcomes remain uncertain and we cannot estimate the potential impact, if any, on the Company's business or financial statements at this time.

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 expense of $2.0 million and $0.2 million for the three and six months ended June 30, 2025, respectively, which resulted in effective tax rates of -1.81% and -0.1%, respectively. The Company recorded a tax benefit of $1.5 million and $2.9 million for the same periods in 2024, respectively, which resulted in effective tax rates of 1.5% and 1.3%, 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 for 2024 and the expense presented for the periods presented for 2025 primarily relate to operations in the UK and realization of related deferred taxes associated with the acquisition of the Proleukin business in UK.

As of June 30, 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.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The Company is currently assessing its impact on its consolidated financial statements.

NOTE 16. SUBSEQUENT EVENTS

On August 7, 2025, the Company announced a strategic restructuring plan with an associated reduction in workforce as a result of a review of current strategic priorities, resource allocation, and cost reduction intended to reduce operating costs, streamline operations and extend its cash runway. The restructuring plan is expected to optimize business performance, prioritize key manufacturing and research and development efforts, as well as reduce headcount by approximately 19 percent. The Company is currently evaluating the accounting impact on the 2025 consolidated financial statements.

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 United Kingdom, or UK, Canada, Australia, Switzerland, and European Union, or EU. In June 2024, we submitted a centralized marketing authorization application, or MAA, to the European Medicines Agency, or the EMA, for lifileucel which was validated and accepted for review by the EMA in August 2024. Following interactions with EMA's Committee for Medicinal Products for Human Use, or CHMP, Iovance notified EMA of its decision to withdraw the MAA and is working to determine a resubmission strategy. An MAA was submitted to the Medicines and Healthcare Products Regulatory Agency in the UK and is on track for potential approval and launch in the first half of 2026. Australia's Therapeutic Goods Administration granted Priority Review to Amtagvi® with a decision anticipated by early 2026, and the Swiss Medic recommended Priority Review ahead of the Swiss regulatory submission planned in the fourth quarter of 2025. A new drug submission, or NDS, was deemed eligible for Notice of Compliance with Conditions, or NOC/c, by Health Canada and submitted in 2024 and approval is expected in the third quarter of 2025, which would make lifileucel the first and only approved therapy in this treatment setting in Canada. 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 UK, Canada, and Australia to prepare for anticipated regulatory approvals and launches 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. More than 1,000 patients have been treated with Iovance TIL cell therapy products manufactured using our proprietary processes across multiple indications in clinical trials and the commercial setting. 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, endometrial 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.

- **Advanced Endometrial Cancer:** IOV-END-201 is a phase 2 clinical trial investigating 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 data suggests IOV-3001 may have a better safety profile and require less frequent dosing compared to Proleukin

- **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. An IND application submission is currently planned for 2026.

Intellectual Property

We have established a leading intellectual property portfolio developed internally and licensed from third parties. We currently own more than 80 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; 11,141,434;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 and six months ended June 30, 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.

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 generally 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 (expense) benefit

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

Results of Operations for the Three and Six Months Ended June 30, 2025 and 2024

Revenue

(in thousands)	Three Months Ended June 30,		Increase (Decrease)		Six Months Ended June 30,		Increase (Decrease)	
	2025	2024	$	%	2025	2024	$	%
Amtagvi®	$ 54,074	$ 12,819	$ 41,255	322	$ 97,645	12,819	$ 84,826	662
Proleukin®	5,878	18,287	(12,409)	(68)	11,631	19,002	(7,371)	(39)
Total product revenue	$ 59,952	$ 31,106	$ 28,846	93	$ 109,276	$ 31,821	$ 77,455	243

Revenue for the three and six months ended June 30, 2025 increased by $28.8 million, or 93%, and $77.5 million, or 243%, compared to the same periods in 2024. 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, and the increase in revenue compared to the prior period was driven by the commercial launch of Amtagvi®, partially offset by a decrease in Proleukin® sales for the same periods in 2025 as compared to 2024 when we experienced significant re-stocking demand from specialty distributors in the U.S. to support ongoing and anticipated infusions followed by the commercial launch of Amtagvi® and as a result of the depletion Proleukin® inventory that was previously with distributors at the time of the acquisition of Proleukin®, or the Acquisition. Through the first quarter of 2024, product revenue was comprised entirely of product sales of Proleukin® in markets outside of the U.S. GTN adjustments did not materially affect net product revenue in the three months ended June 30, 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 June 30,		Increase (Decrease)		Six Months Ended June 30,		Increase (Decrease)	
	2025	2024	$	%	2025	2024	$	%
Cost of sales	$ 56,664	$ 31,368	$ 25,296	81	$ 106,405	$ 38,629	$ 67,776	175
Research and development expense	79,363	62,084	17,279	28	156,242	141,867	14,375	10
Selling, general, and administrative expense	37,699	39,568	(1,869)	(5)	81,624	70,961	10,663	15

Cost of sales

Cost of sales for the three months ended June 30, 2025 increased by $25.3 million, or 81%, compared to the same period in 2024. The increase was driven by (i) a $20.6 million increase in sales of products as well as costs related to the manufacturing of Amtagvi®, (ii) a $7.0 million increase in excess and obsolescence reserve primarily related to excess Proleukin® inventory resulting from a manufacturer contract inherited in the Acquisition for which we cannot yet fully utilize the required purchase quantities, (iii) a $3.3 million increase in 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, and (iv) a $0.2 million increase in non-cash amortization expense for the developed technology intangible assets driven by additional milestone payment paid made in the second quarter of 2024. These increases were partially offset by (i) a $3.0 million decrease in royalties payable related to the decrease in sales of Proleukin®, and a (ii) $2.8 million decrease in non-cash amortization expense for the amortization of the fair value step-up of acquired Proleukin® inventory sold as the acquired inventory continues to be depleted.

Cost of sales for the six months ended June 30, 2025 increased by $67.8 million, or 175%, compared to the same period in 2024. The increase was driven by (i) a $46.4 million increase in sales of products as well as costs related to the manufacturing of Amtagvi®, (ii) a $7.0 million increase in excess and obsolescence reserve primarily related to excess Proleukin® inventory resulting from a manufacturer contract inherited in the Acquisition for which we cannot yet fully utilize the required purchase quantities, (iii) a $18.1 million increase in period costs primarily related to patient drop-off driven by patient health as well as manufacturing results that did not meet required specifications, and (iv) a $1.0 million increase in non-cash amortization expense for the developed technology intangible assets driven by additional milestone payment paid made in the second quarter of 2024. These increases were partially offset by (i) a $1.6 million decrease in royalties payable related to the decrease in sales of Proleukin®, and (ii) a $3.1 million decrease in non-cash amortization expense for the amortization of the fair value step-up of acquired Proleukin® inventory sold as the acquired inventory continues to be depleted.

Research and development expense

Research and development expense for the three months ended June 30, 2025 increased by $17.3 million, or 28%, compared to the same period in 2024. The increase was primarily attributable to (i) a $16.0 million increase in payroll and related costs, primarily driven by an increase in the number of employees (ii) a $6.7 million increase in clinical costs, driven primarily by continued enrollment in TILVANCE-301 and the resumption of the LUN-202 study (iii) $1.8 million increase primarily due to license costs related to the expansion of our information technology infrastructure to support our clinical activities, (iv) a $1.1 million increase in lab and consumable costs to develop next generation candidates, and (v) a $0.3 million increase other costs including travel and facility related costs. The increase was partially offset by a $8.6 million decrease in stock-based compensation expense primarily driven by the number of stock awards granted at lower average stock price.

Research and development expense for the six months ended June 30, 2025 increased by $14.4 million, or 10%, compared to the same period in 2024. The increase was primarily attributable to (i) a $29.9 million increase in payroll and related costs, primarily driven by an increase in the number of employees (ii) a $13.9 million increase in clinical costs, driven primarily by continued enrollment in TILVANCE-301 and the resumption of the LUN-202 study, (iii) a $3.6 million primarily due to license costs related to the expansion of our information technology infrastructure to support our clinical activities, (iv) a $2.6 million increase in lab and consumable costs to develop next generation candidates and (v) $0.2 million increase in other costs including travel and facility related costs. The increase was partially offset by (i) a $30.1 million decrease in manufacturing costs, driven by capitalization of qualified costs for Amtagvi® manufacturing and (ii) a $5.7 million decrease in stock-based compensation expense primarily driven by the number of stock awards granted at lower average stock price, partially offset by an increase in the number of employees.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We 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):

	Three Months Ended June 30,		Increase (Decrease)		Six Months Ended June 30,		Increase (Decrease)	
	2025	2024	$	%	2025	2024	$	%
Direct research and development expense by product candidate								
TIL, including combination therapy								
Lifileucel monotherapy	$ 18,033	$ 16,255	$ 1,778	11	$ 34,214	$ 29,405	$ 4,809	16
Combination Therapy	3,749	4,609	(860)	(19)	7,047	9,030	(1,983)	(22)
Next Generation	2,961	1,130	1,831	162	4,650	5,159	(509)	(10)
Others clinical, preclinical, and research programs under development	6,527	4,077	2,450	60	14,232	6,624	7,608	115
Indirect research and development expense								
Personnel related (excluding stock-based compensation)	28,989	14,171	14,818	105	54,355	44,319	10,036	23
Stock-based compensation expense	6,359	12,976	(6,617)	(51)	16,276	22,473	(6,197)	(28)
Contractors and outside services	2,548	1,477	1,071	73	4,295	4,796	(501)	(10)
Office and facilities	10,197	7,389	2,808	38	21,173	20,061	1,112	6
Total research and development	$ 79,363	$ 62,084	$ 17,279	28	$ 156,242	$ 141,867	$ 14,375	10

Selling, general and administrative expense

Selling, general and administrative expenses for the three months ended June 30, 2025 decreased by $1.9 million, or 5%, compared to the same period in 2024. The decrease was primarily attributable to a $8.8 million decrease in stock-based compensation driven by the number of stock awards granted at lower average stock price. This decrease was partially offset by (i) a $2.8 million increase in costs incurred in support of the marketing and advertising of Amtagvi®, (ii) a $2.6 million increase in payroll and related expenses driven by an increase in the number of employees to support the growth in the overall business, and (iii) a $1.5 million increase in other costs, including costs associated with increased travel, software license costs related to the expansion of our information technology infrastructure.

Selling, general and administrative expenses for the six months ended June 30, 2025 increased by $10.7 million, or 15%, compared to the same period in 2024. The increase was primarily attributable to (i) a $6.7 million increase in payroll and related expense, driven by an increase in headcount to support the growth in the overall business including the commercialization of Amtagvi®, (ii) a $6.0 million increase in costs incurred in support of the distribution and commercialization of Amtagvi® and Proleukin®, (iii) a $1.9 million increase in software license costs related to the expansion of our information technology infrastructure, (iv) a $1.2 million increase in professional services fees, and (v) a $1.3 million increase in other costs, including costs associated with increased travel and legal fees. The increase was offset by a $6.5 million decrease in stock-based compensation primarily driven by the number of stock awards granted at lower average stock price, partially offset by an increase in the number of employees.

Interest and other income, net

(in thousands)	Three Months Ended June 30,		Increase (Decrease)		Six Months Ended June 30,		Increase (Decrease)	
	2025	2024	$	%	2025	2024	$	%
Interest and other income, net	$ 4,104	$ 3,355	$ 749	22	$ 7,324	$ 6,693	$ 631	9

Interest income, net for the three and six months ended June 30, 2025 increased by $0.7 million, or 22%, and $0.6 million, or 9%, compared to the same periods in 2024. The increase was primarily driven by an increase in average investment balances, resulting from net proceeds from recent public and at-the-market financings, partially offset by a slight decrease in interest rates.

Income tax (expense) benefit

(in thousands)	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024	Increase (Decrease) $	Increase (Decrease) %	Six Months Ended June 30, 2025	Six Months Ended June 30, 2024	Increase (Decrease) $	Increase (Decrease) %
Income tax (expense) benefit	$ (1,988)	$ 1,458	$ 3,446	236	$ (150)	$ 2,866	$ 3,016	105

Income tax expense for the three and six months ended June 30, 2025 increased by $3.4 million, or 236%, and $3.0 million , or 105%, respectively, compared to the same periods in 2024. This increase was driven by an adjustment in transfer pricing, true up to tax attributes and deductions associated with the acquisition of the Proleukin business in UK.

Net loss

(in thousands)	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024	Increase (Decrease) $	Increase (Decrease) %	Six Months Ended June 30, 2025	Six Months Ended June 30, 2024	Increase (Decrease) $	Increase (Decrease) %
Net loss	$ (111,658)	$ (97,101)	$ 14,557	15	$ (227,821)	$ (210,077)	$ 17,744	8

Net loss for the three and six months ended June 30, 2025 increased by $14.6 million, or 15%, and $17.7 million, or 8%, compared to the same periods 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 ongoing execution of the launch of Amtagvi®.

Liquidity and Capital Resources

As of June 30, 2025, we had $307.1 million in cash, cash equivalents, short-term investments, and restricted cash ($132.5 million of cash and cash equivalents, $168.7 million in short-term investments, and $5.9 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 ongoing 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 and six months ended June 30, 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.

In August 2025, we approved a strategic restructuring plan with an associated reduction in workforce as a result of a review of current strategic priorities, resource allocation, and cost reduction intended to reduce operating costs, streamline operations and extend our cash runway. The restructuring plan is expected to optimize business performance, prioritize key manufacturing and research and development efforts, as well as reduce headcount by approximately 19 percent.

Corporate Capitalization

As of June 30, 2025, we had outstanding 341,919,364 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, or the Registration Statement. We received $403.7 million in proceeds, net of offering costs, through the sale of 64,030,760 shares of our common stock cumulatively through June 30, 2025 under 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.

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 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):

	Six Months Ended June 30,	
	2025	2024
Net cash (used in) provided by:		
Operating activities	$ (171,141)	$ (220,708)
Investing activities	29,709	(71,287)
Financing activities	156,545	346,401
Net increase (decrease) in cash, cash equivalents and restricted cash*	$ 15,113	$ 54,406

** 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 six months ended June 30, 2025 was $171.1 million as compared to $220.7 million for the same period in 2024. The $49.6 million decrease in cash used in operating activities was driven by a $17.7 million increase in net loss resulting from increased cost of sales and overall growth in our workforce to support our business, partially offset by an increase in revenues generated by sales of Amtagvi® and Proleukin® in the U.S. This increase in net loss was fully offset by a net increase in non-cash charges of $4.5 million and a $62.8 million decrease in net cash used in operating activities related to changes in operating assets and liabilities. The net increase in non-cash charge was primarily driven by excess and obsolescence costs, a decrease in deferred tax benefits related to the operations in the UK, and amortization of intangible assets and right-of-use assets, which were partially offset by lower-stock based compensation expense.

The $62.8 million decrease in net cash used in operating activities related to changes in operating assets and liabilities was driven by a $40.9 million decrease in trade accounts receivable resulting from collection of cash from the sale of our products and a $29.3 million increase in accounts payable and accrued expenses, resulting from timing of vendor invoicing and related payments, partially offset by a $7.4 million increase in net cash used driven primarily by purchases of raw material inventory in support of the commercial demand of Amtagvi®, 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 purchase and maturity of investments, capital expenditures as well as the Acquisition. Net cash provided by investing activities for the six months ended June 30, 2025 was $29.7 million, compared to net cash used by investing activities of $71.3 million for the same period in 2024. The increase in cash provided of $101.0 million was driven by a $57.5 million increase associated with changes in the timing of maturities and purchases of investments, and a $52.6 million decrease in cash used for the Acquisition, net of cash acquired. These increases in cash provided by investing activities were partially offset by a $9.1 million increase in cash utilized to fund capital expenditures.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2025 was $156.5 million compared to net cash provided of $346.4 million for the same period in 2024. The decrease in net cash provided by financing activities of $189.9 million was primarily driven by a decrease in net proceeds of $187.8 million received through the sales of common stock through our “at the market” offering program during the three and six months ended June 30, 2025, as compared to the net proceeds received from our public offering in February 2024 in the first quarter of 2024 and “at the market” offering program for the three and six months ended June 30, 2024. In addition, a $1.6 million decrease in proceeds from the issuance of common stock upon the exercise of stock options and from our employee stock purchase plan program and a $0.5 million increase in tax payments related to shares withheld for vested restricted stock units contributed to the overall decrease in cash provided by financing activities.

Contractual Obligations

The following table summarizes our non-cancellable contractual obligations as of June 30, 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]	$ 86,373	$ 7,724	$ 5,985	$ 4,858	$ 4,964	$ 4,838	$ 58,004
Purchase obligations[2]	25,613	8,233	9,147	8,233	—	—	—
Total[3]	$ 111,986	$ 15,957	$ 15,132	$ 13,091	$ 4,964	$ 4,838	$ 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 $25.6 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 June 30, 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 June 30, 2025. No impairment of intangible assets existed as of June 30, 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 our most recent sales and manufacturing 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 June 30, 2025, we had $250.1 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 June 30, 2025, the fair value of our investment portfolio would increase or decrease by approximately $0.3 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 and six months ended June 30, 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 and six months ended June 30, 2025. No foreign currency exchange risk existed for the three and six months ended June 30, 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 June 30, 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 June 30, 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 and 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;
- 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, 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 June 30, 2025, we had an accumulated deficit of $2.6 billion. In addition, during the six months ended June 30, 2025, we incurred a net loss of $227.8 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 June 30, 2025, we have an accumulated deficit of $2.6 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 June 30, 2025, we had $307.1 million in cash, cash equivalents, short-term investments, and restricted cash ($132.5 million of cash and cash equivalents, $168.7 million in short-term investments, and $5.9 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 undergo reductions in our workforce or other corporate restructuring activities, or 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.

We may be unable to realize the expected benefits from restructuring activities, including workforce reductions, and our business might be adversely affected.*

In August 2025, we announced a strategic restructuring plan with an associated reduction in workforce as a result of a review of current strategic priorities, resource allocation, and cost reduction intended to reduce operating costs, streamline operations and extend our cash runway. The restructuring plan is expected to optimize business performance, prioritize key manufacturing and research and development efforts, as well as reduce headcount by approximately 19 percent. These types of restructuring and cost reduction activities are complex and may result in unintended consequences and costs, such as unforeseen delays in the implementation of our strategic initiatives, business and operational disruptions, decreased employee morale and retention, loss of institutional knowledge

and expertise, and potential impacts on financial reporting. The reduction in our workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we do not successfully manage the impact of the restructuring plan or any other similar activities that we may undertake in the future, we may not achieve the expected costs savings and other expected benefits in the expected timeframe or at all, and our business, financial condition, and results of operations may be materially adversely affected.

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 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 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. On July 4, 2025, the One Big Beautiful Bill Act, or the OBBBA, was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The OBBBA has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. We are currently assessing the impact of the OBBBA on our consolidated financial statements. 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 Minaris Advanced Therapies, Inc., or Minaris, 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 or at 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, Adaptimmune Therapeutics, Alaunos Therapeutics, Biosyngen, GRIT Biotechnology, Immatics, Immunocore, Intima Bioscience, KSQ Therapeutics, 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, results of the Phase 3 M14TIL clinical trial comparing TIL to standard ipilimumab in patients with metastatic melanoma conducted in Europe led by the Netherlands Cancer Institute were published in the New England Journal of Medicine in December 2022 and have been submitted to the European Commission for local, point of care production. 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.

Moreover, in August 2025, management approved a strategic restructuring plan with an associated reduction in workforce of approximately 19 percent as a result of a review of current strategic priorities, resource allocation, and cost reduction intended to reduce operating costs, streamline operations and extend our cash runway. This reduction in our workforce may also make retention of

our current personnel both more important and more challenging. The workforce reduction resulted in the loss of longer-term employees, the loss of institutional knowledge and expertise, and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Given the complexity of our business, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to recruit and retain qualified personnel.

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 and product candidates.*

As noted above, we have limited experience in internal manufacturing our adoptive cell therapy products and product candidates on a commercial scale, as do our partners. Currently our products and product candidates are manufactured internally at our *i*CTC facility and externally by Minaris and other third-party manufacturers. We may take the business decision to optimize our internal manufacturing capacity and focus on expanding our capacity at the *i*CTC facility, based on our analysis of the performance of our facility versus that of Minaris. 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.

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 products and product candidates or modify our manufacturing processes. If we are unable to successfully increase the manufacturing capacity for a product or 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.

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, 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.*

Our results of operations could be adversely affected by general conditions in the global economy, the global financial markets and global political conditions. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflicts in Ukraine and the Middle East, terrorism or other geopolitical events, political tensions between the U.S. and China, or inflation. Sanctions imposed by the U.S. and other countries in response to such conflicts and political tensions may also adversely impact our business, the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability, and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds.

Although our business has not been materially impacted by the ongoing military conflicts in Ukraine or the Middle East, 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 June 30, 2025 we had 341,919,364 shares of common stock outstanding. In addition, we had 33,006,421 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. Also, on May 15, 2025, two putative securities class actions were filed against us and certain of our officers, alleging violations of federal securities laws for allegedly making materially false and misleading statements regarding our expected revenue for fiscal year 2025, which the plaintiffs claim artificially inflated the price of our common stock. On June 5, 2025, two putative shareholder derivative lawsuits were filed, purportedly brought on behalf of Iovance against certain current and former officers and directors of the Company. The lawsuits contain allegations based on or similar to those in the putative securities class actions and claim, among other things, that the defendants breached their fiduciary duties and violated Section 14(a) of the 1934 Act by issuing or causing the Company to issue false and misleading disclosures concerning the Company's financial forecasts for fiscal year 2025. The outcome of these 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 second 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 second 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).
10.1++#	Iovance Biotherapeutics, Inc. 2020 Employee Stock Purchase Plan, as amended.
10.2++#	Iovance Biotherapeutics, Inc. 2018 Equity Incentive Plan, as amended.
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 Principal Financial Officer.
32.1++	Section 1350 Certification of Chief Executive Officer (furnished herewith).
32.2++	Section 1350 Certification of Principal 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.

August 7, 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)

August 7, 2025

By: /s/ Matthew W. Rosinack
Matthew W. Rosinack
Principal Financial and Accounting Officer

IOVANCE BIOTHERAPEUTICS, INC.
2020 EMPLOYEE STOCK PURCHASE PLAN AS AMENDED

1. Establishment, Purpose and Term of Plan.

1.1 Establishment. The Iovance Biotherapeutics, Inc. 2020 Employee Stock Purchase Plan (as amended from time to time, the "**Plan**") is hereby established effective as of June 8, 2020, the date of its initial approval by the stockholders of the Company (the "**Effective Date**").

1.2 Purpose. The purpose of the Plan is to advance the interests of the Company and its stockholders by providing an incentive to attract, retain and reward Eligible Employees of the Participating Company Group and by motivating such persons to contribute to the growth and profitability of the Participating Company Group. The Plan provides such Eligible Employees with an opportunity to acquire a proprietary interest in the Company through the purchase of Stock. The Company intends that the Plan qualify as an "employee stock purchase plan" under Section 423 of the Code (including any amendments or replacements of such section), and the Plan shall be so construed.

1.3 Term of Plan. The Plan shall continue in effect until its termination by the Committee.

2. Definitions and Construction.

2.1 Definitions. Any term not expressly defined in the Plan but defined for purposes of Section 423 of the Code shall have the same definition herein. Whenever used herein, the following terms shall have their respective meanings set forth below:

(a) "**Board**" means the Board of Directors of the Company.

(b) "**Change in Control**" means the occurrence of any one or a combination of the following:

(i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as such term is defined in Rule 13d-3 promulgated under the Exchange Act), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total Fair Market Value or total combined voting power of the Company's then-outstanding securities entitled to vote generally in the election of Directors; provided, however, that a Change in Control shall not be deemed to have occurred if such degree of beneficial ownership results from any of the following: (A) an acquisition by any person who on the Effective Date is the beneficial owner of more than fifty percent (50%) of such voting power, (B) any acquisition directly from the Company, including, without limitation, pursuant to or in connection with a public offering of securities, (C) any acquisition by the Company, (D) any acquisition by a trustee or other fiduciary under an employee benefit plan of a Participating Company or (E) any acquisition by an entity owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of the voting securities of the Company; or

(ii) an Ownership Change Event or series of related Ownership Change Events (collectively, a "**Transaction**") in which the stockholders of the Company immediately before the Transaction do not retain immediately after the Transaction direct or indirect beneficial ownership of more than fifty percent (50%) of the total combined voting power of the outstanding securities entitled to vote generally in the election of Directors or, in the case of an Ownership Change Event described in Section 2.1(p)(iii), the entity to which the assets of the Company were transferred (the "**Transferee**"), as the case may be; or

(iii) approval by the stockholders of a plan of complete liquidation or dissolution of the Company;

provided, however, that a Change in Control shall be deemed not to include a transaction described in subsections (i) or (ii) of this Section 2.1(b) in which a majority of the members of the board of directors of the continuing, surviving or successor entity, or parent thereof, immediately after such transaction is comprised of Incumbent Directors.

For purposes of the preceding sentence, indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities which own the Company or the Transferee, as the case may be, either directly or through one or more subsidiary corporations or other business entities. The Committee shall determine whether multiple acquisitions of the voting securities of the Company and/or multiple Ownership Change Events are related and to be treated in the aggregate as a single Change in Control, and its determination shall be final, binding and conclusive.

(c) "**Code**" means the Internal Revenue Code of 1986, as amended, and any applicable regulations promulgated thereunder.

(d) "**Committee**" means the Compensation Committee and such other committee or subcommittee of the Board, if any, duly appointed to administer the Plan and having such powers in each instance as shall be specified by the Board. If, at any time, there is no committee of the Board then authorized or properly constituted to administer the Plan, the Board shall exercise all of the powers of the Committee granted herein, and, in any event, the Board may in its discretion exercise any or all of such powers.

(e) "**Company**" means Iovance Biotherapeutics, Inc., a Delaware corporation, or any successor corporation thereto.

(f) "**Compensation**" means, with respect to any Offering Period, regular base wages or salary, overtime payments, shift premiums and payments for paid time off, calculated before deduction of (i) any income or employment tax withholdings or (ii) any amounts deferred pursuant to Section 401(k) or Section 125 of the Code. Compensation shall be limited to such amounts actually payable in cash or deferred during the Offering Period. Compensation shall not include (i) sign-on bonuses, annual or other incentive bonuses, commissions, profit-sharing distributions or other incentive-

type payments, (ii) any contributions made by a Participating Company on the Participant's behalf to any employee benefit or welfare plan now or hereafter established (other than amounts deferred pursuant to Section 401(k) or Section 125 of the Code), (iii) payments in lieu of notice, payments pursuant to a severance agreement, termination pay, moving allowances, relocation payments, or (iv) any amounts directly or indirectly paid pursuant to the Plan or any other stock purchase, stock option or other stock-based compensation plan, or any other compensation not expressly included by this Section.

(g) "**Eligible Employee**" means an Employee who meets the requirements set forth in Section 5 for eligibility to participate in the Plan.

(h) "**Employee**" means a person treated as an employee of a Participating Company for purposes of Section 423 of the Code. A Participant shall be deemed to have ceased to be an Employee either upon an actual termination of employment or upon the corporation employing the Participant ceasing to be a Participating Company. For purposes of the Plan, an individual shall not be deemed to have ceased to be an Employee while on any military leave, sick leave, or other bona fide leave of absence approved by the Company of ninety (90) days or less. If an individual's leave of absence exceeds ninety (90) days, the individual shall be deemed to have ceased to be an Employee on the ninety-first (91st) day of such leave unless the individual's right to reemployment with the Participating Company Group is guaranteed either by statute or by contract.

(i) "**Fair Market Value**" means, as of any date:

(i) If, on such date, the Stock is listed or quoted on a national or regional securities exchange or quotation system, the closing price of a share of Stock as quoted on the national or regional securities exchange or quotation system constituting the primary market for the Stock, as reported in The Wall Street Journal or such other source as the Company deems reliable. If the relevant date does not fall on a day on which the Stock has traded on such securities exchange or quotation system, the date on which the Fair Market Value is established shall be the last day on which the Stock was so traded or quoted prior to the relevant date, or such other appropriate day as determined by the Committee, in its discretion.

(ii) If, on the relevant date, the Stock is not then listed on a national or regional securities exchange or quotation system, the Fair Market Value of a share of Stock shall be as determined in good faith by the Committee.

(j) "**Incumbent Director**" means a director who either (i) is a member of the Board as of the Effective Date or (ii) is elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the Incumbent Directors at the time of such election or nomination (but excluding a director who was elected or nominated in connection with an actual or threatened proxy contest relating to the election of directors of the Company).

(k) "**Non-United States Offering**" means a separate Offering covering Eligible Employees of one or more Participating Companies whose Eligible

Employees are subject to a prohibition under applicable law on payroll deductions, as described in Section 11.1(b).

(l) "**Offering**" means an offering of Stock pursuant to the Plan, as provided in Section 6.

(m) "**Offering Date**" means, for any Offering Period, the first day of such Offering Period.

(n) "**Offering Period**" means a period, established by the Committee in accordance with Section 6, during which an Offering is outstanding.

(o) "**Officer**" means any person designated by the Board as an officer of the Company.

(p) "**Ownership Change Event**" means the occurrence of any of the following with respect to the Company: (i) the direct or indirect sale or exchange in a single or series of related transactions by the stockholders of the Company of securities of the Company representing more than fifty percent (50%) of the total combined voting power of the Company's then outstanding securities entitled to vote generally in the election of Directors; (ii) a merger or consolidation in which the Company is a party; or (iii) the sale, exchange, or transfer of all or substantially all of the assets of the Company (other than a sale, exchange or transfer to one or more subsidiaries of the Company).

(q) "**Parent Corporation**" means any present or future "parent corporation" of the Company, as defined in Section 424(e) of the Code.

(r) "**Participant**" means an Eligible Employee who has become a participant in an Offering Period in accordance with Section 7 and remains a participant in accordance with the Plan.

(s) "**Participating Company**" means the Company and any Parent Corporation or Subsidiary Corporation designated by the Committee as a corporation the Employees of which may, if Eligible Employees, participate in the Plan. The Committee shall have the discretion to determine from time to time which Parent Corporations or Subsidiary Corporations shall be Participating Companies. The Committee shall designate from time to time and set forth in Exhibit A to this Plan those Participating Companies whose Eligible Employees may participate in the Plan.

(t) "**Participating Company Group**" means, at any point in time, the Company and all other corporations collectively which are then Participating Companies.

(u) "**Purchase Date**" means, for any Offering Period, the last day of such Offering Period, or, if so determined by the Committee, the last day of each Purchase Period occurring within such Offering Period.

(v) "**Purchase Period**" means a period, established by the Committee in accordance with Section 6, included within an Offering Period and on the final date of which outstanding Purchase Rights are exercised.

(w) "**Purchase Price**" means the price at which a share of Stock may be purchased under the Plan, as determined in accordance with Section 9.

(x) "**Purchase Right**" means an option granted to a Participant pursuant to the Plan to purchase such shares of Stock as provided in Section 8, which the Participant may or may not exercise during the Offering Period in which such option is outstanding. Such option arises from the right of a Participant to withdraw any payroll deductions or other funds accumulated on behalf of the Participant and not previously applied to the purchase of Stock under the Plan, and to terminate participation in the Plan at any time during an Offering Period.

(y) "**Securities Act**" means the Securities Act of 1933, as amended.

(z) "**Stock**" means the common stock of the Company, as adjusted from time to time in accordance with Section 4.2.

(aa) "**Subscription Agreement**" means a written or electronic agreement, in such form as specified by the Company, stating an Employee's election to participate in the Plan and authorizing payroll deductions under the Plan from the Employee's Compensation or other method of payment authorized by the Committee pursuant to Section 11.1(b).

(bb) "**Subscription Date**" means the last business day prior to the Offering Date of an Offering Period or such earlier date as the Company shall establish.

(cc) "**Subsidiary Corporation**" means any present or future "subsidiary corporation" of the Company, as defined in Section 424(f) of the Code.

2.2 Construction. Captions and titles contained herein are for convenience only and shall not affect the meaning or interpretation of any provision of the Plan. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.

3. Administration.

3.1 Administration by the Committee. The Plan shall be administered by the Committee. All questions of interpretation of the Plan, of any form of agreement or other document employed by the Company in the administration of the Plan, or of any Purchase Right shall be determined by the Committee, and such determinations shall be final, binding and conclusive upon all persons having an interest in the Plan or the Purchase Right, unless fraudulent or made in bad faith. Subject to the provisions of the Plan, the Committee shall determine all of the relevant terms and conditions of Purchase Rights; provided, however, that all Participants granted Purchase Rights pursuant to an Offering shall have the same rights and

privileges within the meaning of Section 423(b)(5) of the Code. Any and all actions, decisions and determinations taken or made by the Committee in the exercise of its discretion pursuant to the Plan or any agreement thereunder (other than determining questions of interpretation pursuant to the second sentence of this Section 3.1) shall be final, binding and conclusive upon all persons having an interest therein. All expenses incurred in connection with the administration of the Plan shall be paid by the Company.

3.2 Authority of Officers. Any Officer shall have the authority to act on behalf of the Company with respect to any matter, right, obligation, determination or election that is the responsibility of or that is allocated to the Company herein, provided that the Officer has apparent authority with respect to such matter, right, obligation, determination or election.

3.3 Power to Adopt Sub-Plans or Varying Terms with Respect to Non-U.S. Employees. The Committee shall have the power, in its discretion, to adopt one or more sub-plans of the Plan as the Committee deems necessary or desirable to comply with the laws or regulations, tax policy, accounting principles or custom of foreign jurisdictions applicable to employees of a subsidiary business entity of the Company, provided that any such sub-plan shall not be within the scope of an "employee stock purchase plan" within the meaning of Section 423 of the Code. Any of the provisions of any such sub-plan may supersede the provisions of this Plan, other than Section 4. Except as superseded by the provisions of a sub-plan, the provisions of this Plan shall govern such sub-plan. Alternatively and in order to comply with the laws of a foreign jurisdiction, the Committee shall have the power, in its discretion, to grant Purchase Rights in an Offering to citizens or residents of a non-U.S. jurisdiction (without regard to whether they are also citizens of the United States or resident aliens) that provide terms which are less favorable than the terms of Purchase Rights granted under the same Offering to Employees resident in the United States.

3.4 Power to Establish Separate Offerings with Varying Terms. The Committee shall have the power, in its discretion, to establish separate, simultaneous or overlapping Offerings having different terms and conditions and to designate the Participating Company or Companies that may participate in a particular Offering, provided that each Offering shall individually comply with the terms of the Plan and the requirements of Section 423(b)(5) of the Code that all Participants granted Purchase Rights pursuant to such Offering shall have the same rights and privileges within the meaning of such section.

3.5 Policies and Procedures Established by the Company. Without regard to whether any Participant's Purchase Right may be considered adversely affected, the Company may, from time to time, consistent with the Plan and the requirements of Section 423 of the Code, establish, change or terminate such rules, guidelines, policies, procedures, limitations, or adjustments as deemed advisable by the Company, in its discretion, for the proper administration of the Plan, including, without limitation, (a) a minimum payroll deduction amount required for participation in an Offering, (b) a limitation on the frequency or number of changes permitted in the rate of payroll deduction during an Offering, (c) an exchange ratio applicable to amounts withheld or paid in a currency other than United States dollars, (d) a payroll deduction greater than or less than the amount designated by a Participant in order to adjust for the Company's delay or mistake in processing a Subscription Agreement or in otherwise effecting a Participant's election under the Plan or as advisable to comply with the requirements of Section 423 of the

Code, and (e) determination of the date and manner by which the Fair Market Value of a share of Stock is determined for purposes of administration of the Plan. All such actions by the Company shall be taken consistent with the requirements under Section 423(b)(5) of the Code that all Participants granted Purchase Rights pursuant to an Offering shall have the same rights and privileges within the meaning of such section, except as otherwise permitted by Section 3.3 and the regulations under Section 423 of the Code.

3.6 Indemnification. In addition to such other rights of indemnification as they may have as members of the Board or the Committee or as officers or employees of the Participating Company Group, to the extent permitted by applicable law, members of the Board or the Committee and any officers or employees of the Participating Company Group to whom authority to act for the Board, the Committee or the Company is delegated shall be indemnified by the Company against all reasonable expenses, including attorneys' fees, actually and necessarily incurred in connection with the defense of any action, suit or proceeding, or in connection with any appeal therein, to which they or any of them may be a party by reason of any action taken or failure to act under or in connection with the Plan, or any right granted hereunder, and against all amounts paid by them in settlement thereof (provided such settlement is approved by independent legal counsel selected by the Company) or paid by them in satisfaction of a judgment in any such action, suit or proceeding, except in relation to matters as to which it shall be adjudged in such action, suit or proceeding that such person is liable for gross negligence, bad faith or intentional misconduct in duties; provided, however, that within sixty (60) days after the institution of such action, suit or proceeding, such person shall offer to the Company, in writing, the opportunity at its own expense to handle and defend the same.

4. Shares Subject to Plan.

4.1 Maximum Number of Shares Issuable. Subject to adjustment as provided in Sections 4.2, the maximum aggregate number of shares of Stock that may be issued under the Plan shall be 2,900,000 and shall consist of authorized but unissued or reacquired shares of Stock, or any combination thereof. If an outstanding Purchase Right for any reason expires or is terminated or canceled, the shares of Stock allocable to the unexercised portion of that Purchase Right shall again be available for issuance under the Plan.

4.2 Adjustments for Changes in Capital Structure. Subject to any required action by the stockholders of the Company and the requirements of Section 424 of the Code to the extent applicable, in the event of any change in the Stock effected without receipt of consideration by the Company, whether through merger, consolidation, reorganization, reincorporation, recapitalization, reclassification, stock dividend, stock split, reverse stock split, split-up, split-off, spin-off, combination of shares, exchange of shares, or similar change in the capital structure of the Company, or in the event of payment of a dividend or distribution to the stockholders of the Company in a form other than Stock (excepting regular, periodic cash dividends) that has a material effect on the Fair Market Value of shares of Stock, appropriate and proportionate adjustments shall be made in the number and kind of shares subject to the Plan, the Annual Increase, the limit on the shares which may be purchased by any Participant during an Offering (as described in Sections 8.1 and 8.2) and each Purchase Right, and in the Purchase Price in order to prevent dilution or enlargement of Participants' rights under the Plan. For purposes of the foregoing, conversion of any convertible securities of the Company shall not be

treated as "effected without receipt of consideration by the Company." If a majority of the shares which are of the same class as the shares that are subject to outstanding Purchase Rights are exchanged for, converted into, or otherwise become (whether or not pursuant to an Ownership Change Event) shares of another corporation (the "**New Shares**"), the Committee may unilaterally amend the outstanding Purchase Rights to provide that such Purchase Rights are for New Shares. In the event of any such amendment, the number of shares subject to, and the exercise price per share of, the outstanding Purchase Rights shall be adjusted in a fair and equitable manner as determined by the Committee, in its discretion. Any fractional share resulting from an adjustment pursuant to this Section shall be rounded down to the nearest whole number, and in no event may the Purchase Price be decreased to an amount less than the par value, if any, of the stock subject to the Purchase Right. The adjustments determined by the Committee pursuant to this Section 4.2 shall be final, binding and conclusive.

5. Eligibility.

5.1 Employees Eligible to Participate. Each Employee of a Participating Company is eligible to participate in the Plan and shall be deemed an Eligible Employee, except the following:

(a) Any Employee who is customarily employed by the Participating Company Group for twenty (20) hours or less per week; or

(b) Any Employee who is customarily employed by the Participating Company Group for not more than five (5) months in any calendar year.

5.2 Exclusion of Certain Stockholders. Notwithstanding any provision of the Plan to the contrary, no Employee shall be treated as an Eligible Employee and granted a Purchase Right under the Plan if, immediately after such grant, the Employee would own, or hold options to purchase, stock of the Company or of any Parent Corporation or Subsidiary Corporation possessing five percent (5%) or more of the total combined voting power or value of all classes of stock of such corporation, as determined in accordance with Section 423(b)(3) of the Code. For purposes of this Section 5.2, the attribution rules of Section 424(d) of the Code shall apply in determining the stock ownership of such Employee.

5.3 Determination by Company. The Company shall determine in good faith and in the exercise of its discretion whether an individual has become or has ceased to be an Employee or an Eligible Employee and the effective date of such individual's attainment or termination of such status, as the case may be. For purposes of an individual's participation in or other rights, if any, under the Plan as of the time of the Company's determination of whether or not the individual is an Employee, all such determinations by the Company shall be final, binding and conclusive as to such rights, if any, notwithstanding that the Company or any court of law or governmental agency subsequently makes a contrary determination as to such individual's status as an Employee.

6. Offerings.

The Plan shall be implemented by sequential Offerings of approximately six (6) months' duration or such other duration as the Committee shall determine. Offering Periods

shall commence on or about the fifteenth (15th) days of June and December each year and end on or about the fourteenth (14th) day of the next December and June, respectively, occurring thereafter. Notwithstanding the foregoing, the Committee may establish additional or alternative concurrent, sequential or overlapping Offering Periods, a different duration for one or more Offering Periods or different commencing or ending dates for such Offering Periods; provided, however, that no Offering Period may have a duration exceeding twenty-seven (27) months. If the Committee shall so determine in its discretion, each Offering Period may consist of two (2) or more consecutive Purchase Periods having such duration as the Committee shall specify, and the last day of each such Purchase Period shall be a Purchase Date. If the first or last day of an Offering Period or a Purchase Period is not a day on which the principal stock exchange or quotation system on which the Stock is then listed is open for trading, the Company shall specify the trading day that will be deemed the first or last day, as the case may be, of the Offering Period or Purchase Period.

7. Participation in the Plan.

7.1 Initial Participation. An Eligible Employee may become a Participant in an Offering Period by delivering a properly completed written or electronic Subscription Agreement to the Company office or representative designated by the Company (including a third-party administrator designated by the Company) not later than the close of business on the Subscription Date established by the Company for that Offering Period. An Eligible Employee who does not deliver a properly completed Subscription Agreement in the manner permitted or required on or before the Subscription Date for an Offering Period shall not participate in the Plan for that Offering Period or for any subsequent Offering Period unless the Eligible Employee subsequently delivers a properly completed Subscription Agreement to the appropriate Company office or representative on or before the Subscription Date for such subsequent Offering Period. An Employee who becomes an Eligible Employee after the Offering Date of an Offering Period shall not be eligible to participate in that Offering Period but may participate in any subsequent Offering Period provided the Employee is still an Eligible Employee as of the Offering Date of such subsequent Offering Period.

7.2 Continued Participation. A Participant shall automatically participate in the next Offering Period commencing immediately after the final Purchase Date of each Offering Period in which the Participant participates provided that the Participant remains an Eligible Employee on the Offering Date of the new Offering Period and has not either (a) withdrawn from the Plan pursuant to Section 12.1, or (b) terminated employment or otherwise ceased to be an Eligible Employee as provided in Section 13. A Participant who may automatically participate in a subsequent Offering Period, as provided in this Section, is not required to deliver any additional Subscription Agreement for the subsequent Offering Period in order to continue participation in the Plan. However, a Participant may deliver a new Subscription Agreement for a subsequent Offering Period in accordance with the procedures set forth in Section 7.1 if the Participant desires to change any of the elections contained in the Participant's then effective Subscription Agreement.

8. Right to Purchase Shares.

8.1 Grant of Purchase Right. Except as otherwise provided below, on the Offering Date of each Offering Period, each Participant in such Offering Period shall be granted

automatically a Purchase Right consisting of an option to purchase the lesser of (a) that number of whole shares of Stock determined by dividing the Dollar Limit (determined as provided below) by the Fair Market Value of a share of Stock on such Offering Date or (b) the Share Limit (determined as provided below). The Committee may, in its discretion and prior to the Offering Date of any Offering Period, (i) change the method of, or any of the foregoing factors in, determining the number of shares of Stock subject to Purchase Rights to be granted on such Offering Date, or (ii) specify a maximum aggregate number of shares that may be purchased by all Participants in an Offering or on any Purchase Date within an Offering Period. No Purchase Right shall be granted on an Offering Date to any person who is not, on such Offering Date, an Eligible Employee. For the purposes of this Section, the *"**Dollar Limit**"* shall be determined by multiplying $2,083.33 by the number of months (rounded to the nearest whole month) in the Offering Period and rounding to the nearest whole dollar, and the *"**Share Limit**"* shall be determined by multiplying 420 shares by the number of months (rounded to the nearest whole month) in the Offering Period and rounding to the nearest whole share.

8.2 Calendar Year Purchase Limitation. Notwithstanding any provision of the Plan to the contrary, no Participant shall be granted a Purchase Right which permits his or her right to purchase shares of Stock under the Plan to accrue at a rate which, when aggregated with such Participant's rights to purchase shares under all other employee stock purchase plans of a Participating Company intended to meet the requirements of Section 423 of the Code, exceeds Twenty-Five Thousand Dollars ($25,000) in Fair Market Value (or such other limit, if any, as may be imposed by the Code) for each calendar year in which such Purchase Right is outstanding at any time. For purposes of the preceding sentence, the Fair Market Value of shares purchased during a given Offering Period shall be determined as of the Offering Date for such Offering Period. The limitation described in this Section shall be applied in conformance with Section 423(b)(8) of the Code and the regulations thereunder.

9. Purchase Price.

The Purchase Price at which each share of Stock may be acquired in an Offering Period upon the exercise of all or any portion of a Purchase Right shall be established by the Committee; provided, however, that the Purchase Price on each Purchase Date shall not be less than eighty-five percent (85%) of the lesser of (a) the Fair Market Value of a share of Stock on the Offering Date of the Offering Period or (b) the Fair Market Value of a share of Stock on the Purchase Date. Subject to adjustment as provided by the Plan and unless otherwise provided by the Committee, the Purchase Price for each Offering Period shall be eighty-five percent (85%) of the lesser of (a) the Fair Market Value of a share of Stock on the Offering Date of the Offering Period or (b) the Fair Market Value of a share of Stock on the Purchase Date.

10. Accumulation of Purchase Price through Payroll Deduction.

Except as provided in Section 11.1(b) with respect to a Non-United States Offering, shares of Stock acquired pursuant to the exercise of all or any portion of a Purchase Right may be paid for only by means of payroll deductions from the Participant's Compensation accumulated during the Offering Period for which such Purchase Right was granted, subject to the following:

10.1 Amount of Payroll Deductions. Except as otherwise provided herein, the amount to be deducted under the Plan from a Participant's Compensation on each pay day during an Offering Period shall be determined by the Participant's Subscription Agreement. The Subscription Agreement shall set forth the percentage of the Participant's Compensation to be deducted on each pay day during an Offering Period in whole percentages of not less than one percent (1%) (except as a result of an election pursuant to Section 10.3 to stop payroll deductions effective following the first pay day during an Offering) or more than twenty percent (20%). The Committee may change the foregoing limits on payroll deductions effective as of any Offering Date.

10.2 Commencement of Payroll Deductions. Payroll deductions shall commence on the first pay day following the Offering Date and shall continue to the end of the Offering Period unless sooner altered or terminated as provided herein.

10.3 Election to Decrease or Stop Payroll Deductions. During an Offering Period, a Participant may elect to decrease the rate of or to stop deductions from his or her Compensation by delivering to the Company office or representative designated by the Company (including a third-party administrator designated by the Company) an amended Subscription Agreement authorizing such change on or before the "Change Notice Date." The "**Change Notice Date**" shall be a date prior to the beginning of the first pay period for which such election is to be effective as established by the Company from time to time and announced to the Participants. A Participant who elects, effective following the first pay day of an Offering Period, to decrease the rate of his or her payroll deductions to zero percent (0%) shall nevertheless remain a Participant in such Offering Period unless the Participant withdraws from the Plan as provided in Section 12.1.

10.4 Administrative Suspension of Payroll Deductions. The Company may, in its discretion, suspend a Participant's payroll deductions under the Plan as the Company deems advisable to avoid accumulating payroll deductions in excess of the amount that could reasonably be anticipated to purchase the maximum number of shares of Stock permitted (a) under the Participant's Purchase Right or (b) during a calendar year under the limit set forth in Section 8.2. Unless the Participant has either withdrawn from the Plan as provided in Section 12.1 or has ceased to be an Eligible Employee, suspended payroll deductions shall be resumed at the rate specified in the Participant's then effective Subscription Agreement either (i) at the beginning of the next Offering Period if the reason for suspension was clause (a) in the preceding sentence, or (ii) at the beginning of the next Offering Period having a first Purchase Date that falls within the subsequent calendar year if the reason for suspension was clause (b) in the preceding sentence.

10.5 Participant Accounts. Individual bookkeeping accounts shall be maintained for each Participant. All payroll deductions from a Participant's Compensation (and other amounts received from a non-United States Participant pursuant to Section 11.1(b)) shall be credited to such Participant's Plan account and shall be deposited with the general funds of the Company. All such amounts received or held by the Company may be used by the Company for any corporate purpose.

10.6 No Interest Paid. Interest shall not be paid on sums deducted from a Participant's Compensation pursuant to the Plan or otherwise credited to the Participant's Plan account.

11. Purchase of Shares.

11.1 Exercise of Purchase Right.

(a) Generally. Except as provided in Section 11.1(b), on each Purchase Date of an Offering Period, each Participant who has not withdrawn from the Plan and whose participation in the Offering has not otherwise terminated before such Purchase Date shall automatically acquire pursuant to the exercise of the Participant's Purchase Right the number of whole shares of Stock determined by dividing (a) the total amount of the Participant's payroll deductions accumulated in the Participant's Plan account during the Offering Period and not previously applied toward the purchase of Stock by (b) the Purchase Price. However, in no event shall the number of shares purchased by the Participant during an Offering Period exceed the number of shares subject to the Participant's Purchase Right. No shares of Stock shall be purchased on a Purchase Date on behalf of a Participant whose participation in the Offering or the Plan has terminated before such Purchase Date.

(b) Purchase by Non-United States Participants for Whom Payroll Deductions Are Prohibited by Applicable Law. Notwithstanding Section 11.1(a), where payroll deductions on behalf of Participants who are citizens or residents of countries other than the United States (without regard to whether they are also citizens of the United States or resident aliens) are prohibited by applicable law, the Committee may establish a separate Offering (a "**Non-United States Offering**") covering all Eligible Employees of one or more Participating Companies subject to such prohibition on payroll deductions. The Non-United States Offering shall provide another method for payment of the Purchase Price with such terms and conditions as shall be administratively convenient and comply with applicable law. On each Purchase Date of the Offering Period applicable to a Non-United States Offering, each Participant who has not withdrawn from the Plan and whose participation in such Offering Period has not otherwise terminated before such Purchase Date shall automatically acquire pursuant to the exercise of the Participant's Purchase Right a number of whole shares of Stock determined in accordance with Section 11.1(a) to the extent of the total amount of the Participant's Plan account balance accumulated during the Offering Period in accordance with the method established by the Committee and not previously applied toward the purchase of Stock. However, in no event shall the number of shares purchased by a Participant during such Offering Period exceed the number of shares subject to the Participant's Purchase Right. The Company shall refund to a Participant in a Non-United States Offering in accordance with Section 11.4 any excess Purchase Price payment received from such Participant.

11.2 Pro Rata Allocation of Shares. If the number of shares of Stock which might be purchased by all Participants on a Purchase Date exceeds the number of shares of Stock remaining available for issuance under the Plan or the maximum aggregate number of shares of

Stock that may be purchased on such Purchase Date pursuant to a limit established by the Committee pursuant to Section 8.1, the Company shall make a pro rata allocation of the shares available in as uniform a manner as practicable and as the Company determines to be equitable. Any fractional share resulting from such pro rata allocation to any Participant shall be disregarded.

11.3 Delivery of Title to Shares. Subject to any governing rules or regulations, as soon as practicable after each Purchase Date, the Company shall issue or cause to be issued to or for the benefit of each Participant the shares of Stock acquired by the Participant on such Purchase Date by means of one or more of the following: (a) by delivering to the Participant evidence of book entry shares of Stock credited to the account of the Participant, (b) by depositing such shares of Stock for the benefit of the Participant with any broker with which the Participant has an account relationship, or (c) by delivering such shares of Stock to the Participant in certificate form.

11.4 Return of Plan Account Balance. Any cash balance remaining in a Participant's Plan account following any Purchase Date shall be refunded to the Participant as soon as practicable after such Purchase Date. However, if the cash balance to be returned to a Participant pursuant to the preceding sentence is less than the amount that would have been necessary to purchase an additional whole share of Stock on such Purchase Date, the Company may retain the cash balance in the Participant's Plan account to be applied toward the purchase of shares of Stock in the subsequent Purchase Period or Offering Period.

11.5 Tax Withholding. At the time a Participant's Purchase Right is exercised, in whole or in part, or at the time a Participant disposes of some or all of the shares of Stock he or she acquires under the Plan, the Participant shall make adequate provision for the federal, state, local and foreign taxes (including social insurance), if any, required to be withheld by any Participating Company upon exercise of the Purchase Right or upon such disposition of shares, respectively. A Participating Company may, but shall not be obligated to, withhold from the Participant's compensation the amount necessary to meet such withholding obligations.

11.6 Expiration of Purchase Right. Any portion of a Participant's Purchase Right remaining unexercised after the end of the Offering Period to which the Purchase Right relates shall expire immediately upon the end of the Offering Period.

11.7 Provision of Reports and Stockholder Information to Participants. Each Participant who has exercised all or part of his or her Purchase Right shall receive, as soon as practicable after the Purchase Date, a report of such Participant's Plan account setting forth the total amount credited to his or her Plan account prior to such exercise, the number of shares of Stock purchased, the Purchase Price for such shares, the date of purchase and the cash balance, if any, remaining immediately after such purchase that is to be refunded or retained in the Participant's Plan account pursuant to Section 11.4. The report required by this Section may be delivered in such form and by such means, including by electronic transmission, as the Company may determine. In addition, each Participant shall be provided information concerning the Company equivalent to that information provided generally to the Company's common stockholders.

12. Withdrawal from Plan.

12.1 Voluntary Withdrawal from the Plan. A Participant may withdraw from the Plan by signing and delivering to the Company office or representative designated by the Company (including a third-party administrator designated by the Company) a written or electronic notice of withdrawal on a form provided by the Company for this purpose. Such withdrawal may be elected at any time prior to the end of an Offering Period; provided, however, that if a Participant withdraws from the Plan after a Purchase Date, the withdrawal shall not affect shares of Stock acquired by the Participant on such Purchase Date. A Participant who voluntarily withdraws from the Plan is prohibited from resuming participation in the Plan in the same Offering from which he or she withdrew, but may participate in any subsequent Offering by again satisfying the requirements of Sections 5 and 7.1. The Company may impose, from time to time, a requirement that the notice of withdrawal from the Plan be on file with the Company office or representative designated by the Company for a reasonable period prior to the effectiveness of the Participant's withdrawal.

12.2 Return of Plan Account Balance. Upon a Participant's voluntary withdrawal from the Plan pursuant to Section 12.1, the Participant's accumulated Plan account balance which has not been applied toward the purchase of shares of Stock shall be refunded to the Participant as soon as practicable after the withdrawal, without the payment of any interest, and the Participant's interest in the Plan and the Offering shall terminate. Such amounts to be refunded in accordance with this Section may not be applied to any other Offering under the Plan.

13. Termination of Employment or Eligibility.

Upon a Participant's ceasing, prior to a Purchase Date, to be an Employee of the Participating Company Group for any reason, including retirement, disability or death, or upon the failure of a Participant to remain an Eligible Employee, the Participant's participation in the Plan shall terminate immediately. In such event, the Participant's Plan account balance which has not been applied toward the purchase of shares of Stock shall, as soon as practicable, be returned to the Participant or, in the case of the Participant's death, to the Participant's beneficiary designated in accordance with Section 20, if any, or legal representative, and all of the Participant's rights under the Plan shall terminate. Interest shall not be paid on sums returned pursuant to this Section 13. A Participant whose participation has been so terminated may again become eligible to participate in the Plan by satisfying the requirements of Sections 5 and 7.1.

14. Effect of Change in Control on Purchase Rights.

In the event of a Change in Control, the surviving, continuing, successor, or purchasing corporation or parent thereof, as the case may be (the "**Acquiring Corporation**"), may, without the consent of any Participant, assume or continue the Company's rights and obligations under outstanding Purchase Rights or substitute substantially equivalent purchase rights for the Acquiring Corporation's stock. If the Acquiring Corporation elects not to assume, continue or substitute for the outstanding Purchase Rights, the Purchase Date of the then current Offering Period shall be accelerated to a date before the date of the Change in Control specified by the Committee, but the number of shares of Stock subject to outstanding Purchase Rights

shall not be adjusted. All Purchase Rights which are neither assumed or continued by the Acquiring Corporation in connection with the Change in Control nor exercised as of the date of the Change in Control shall terminate and cease to be outstanding effective as of the date of the Change in Control.

15. Nontransferability of Purchase Rights.

Neither payroll deductions or other amounts credited to a Participant's Plan account nor a Participant's Purchase Right may be assigned, transferred, pledged or otherwise disposed of in any manner other than as provided by the Plan or by will or the laws of descent and distribution. (A beneficiary designation pursuant to Section 20 shall not be treated as a disposition for this purpose.) Any such attempted assignment, transfer, pledge or other disposition shall be without effect, except that the Company may treat such act as an election to withdraw from the Plan as provided in Section 12.1. A Purchase Right shall be exercisable during the lifetime of the Participant only by the Participant.

16. Compliance with Securities Law.

The issuance of shares under the Plan shall be subject to compliance with all applicable requirements of federal, state and foreign law with respect to such securities. A Purchase Right may not be exercised if the issuance of shares upon such exercise would constitute a violation of any applicable federal, state or foreign securities laws or other law or regulations or the requirements of any securities exchange or market system upon which the Stock may then be listed. In addition, no Purchase Right may be exercised unless (a) a registration statement under the Securities Act shall at the time of exercise of the Purchase Right be in effect with respect to the shares issuable upon exercise of the Purchase Right, or (b) in the opinion of legal counsel to the Company, the shares issuable upon exercise of the Purchase Right may be issued in accordance with the terms of an applicable exemption from the registration requirements of the Securities Act. The inability of the Company to obtain from any regulatory body having jurisdiction the authority, if any, deemed by the Company's legal counsel to be necessary to the lawful issuance and sale of any shares under the Plan shall relieve the Company of any liability in respect of the failure to issue or sell such shares as to which such requisite authority shall not have been obtained. As a condition to the exercise of a Purchase Right, the Company may require the Participant to satisfy any qualifications that may be necessary or appropriate, to evidence compliance with any applicable law or regulation, and to make any representation or warranty with respect thereto as may be requested by the Company.

17. Rights as a Stockholder and Employee.

A Participant shall have no rights as a stockholder by virtue of the Participant's participation in the Plan until the date of the issuance of the shares of Stock purchased pursuant to the exercise of the Participant's Purchase Right (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment shall be made for dividends, distributions or other rights for which the record date is prior to the date such shares are issued, except as provided in Section 4.2. Nothing herein shall confer upon a Participant any right to continue in the employ of the Participating Company Group or interfere

in any way with any right of the Participating Company Group to terminate the Participant's employment at any time.

18. Notification of Disposition of Shares.

The Company may require the Participant to give the Company prompt notice of any disposition of shares of Stock acquired by exercise of a Purchase Right. The Company may require that until such time as a Participant disposes of shares of Stock acquired upon exercise of a Purchase Right, the Participant shall hold all such shares in the Participant's name until the later of two years after the date of grant of such Purchase Right or one year after the date of exercise of such Purchase Right. The Company may direct that the certificates evidencing shares of Stock acquired by exercise of a Purchase Right refer to such requirement to give prompt notice of disposition.

19. Legends.

The Company may at any time place legends or other identifying symbols referencing any applicable federal, state or foreign securities law restrictions or any provision convenient in the administration of the Plan on some or all of the certificates representing shares of Stock issued under the Plan. The Participant shall, at the request of the Company, promptly present to the Company any and all certificates representing shares acquired pursuant to a Purchase Right in the possession of the Participant in order to carry out the provisions of this Section. Unless otherwise specified by the Company, legends placed on such certificates may include but shall not be limited to the following:

"THE SHARES EVIDENCED BY THIS CERTIFICATE WERE ISSUED BY THE CORPORATION TO THE REGISTERED HOLDER UPON THE PURCHASE OF SHARES UNDER AN EMPLOYEE STOCK PURCHASE PLAN AS DEFINED IN SECTION 423 OF THE INTERNAL REVENUE CODE OF 1986, AS AMENDED. THE TRANSFER AGENT FOR THE SHARES EVIDENCED HEREBY SHALL NOTIFY THE CORPORATION IMMEDIATELY OF ANY TRANSFER OF THE SHARES BY THE REGISTERED HOLDER HEREOF. THE REGISTERED HOLDER SHALL HOLD ALL SHARES PURCHASED UNDER THE PLAN IN THE REGISTERED HOLDER'S NAME (AND NOT IN THE NAME OF ANY NOMINEE)."

20. Designation of Beneficiary.

20.1 Designation Procedure. Subject to local laws and procedures, a Participant may file a written designation of a beneficiary who is to receive (a) shares and cash, if any, from the Participant's Plan account if the Participant dies subsequent to a Purchase Date but prior to delivery to the Participant of such shares and cash, or (b) cash, if any, from the Participant's Plan account if the Participant dies prior to the exercise of the Participant's Purchase Right. If a married Participant designates a beneficiary other than the Participant's spouse, the effectiveness of such designation may be subject to the consent of the Participant's spouse. A Participant may change his or her beneficiary designation at any time by written notice to the Company.

20.2 Absence of Beneficiary Designation. If a Participant dies without an effective designation pursuant to Section 20.1 of a beneficiary who is living at the time of the Participant's death, the Company shall deliver any shares or cash credited to the Participant's Plan account to the Participant's legal representative or as otherwise required by applicable law.

21. Notices.

All notices or other communications by a Participant to the Company under or in connection with the Plan shall be deemed to have been duly given when received in the form specified by the Company at the location, or by the person, designated by the Company for the receipt thereof.

22. Amendment or Termination of the Plan.

The Committee may at any time amend, suspend or terminate the Plan, except that (a) no such amendment, suspension or termination shall affect Purchase Rights previously granted under the Plan unless expressly provided by the Committee, and (b) no such amendment, suspension or termination may adversely affect a Purchase Right previously granted under the Plan without the consent of the Participant, except to the extent permitted by the Plan or as may be necessary to qualify the Plan as an employee stock purchase plan pursuant to Section 423 of the Code or to comply with any applicable law, regulation or rule. In addition, an amendment to the Plan must be approved by the stockholders of the Company within twelve (12) months of the adoption of such amendment if such amendment would authorize the sale of more shares than are then authorized for issuance under the Plan or would change the definition of the corporations that may be designated by the Committee as Participating Companies. Notwithstanding the foregoing, in the event that the Committee determines that continuation of the Plan or an Offering would result in unfavorable financial accounting consequences to the Company, the Committee may, in its discretion and without the consent of any Participant, including with respect to an Offering Period then in progress: (i) terminate the Plan or any Offering Period, (ii) accelerate the Purchase Date of any Offering Period, (iii) reduce the discount or the method of determining the Purchase Price in any Offering Period (e.g., by determining the Purchase Price solely on the basis of the Fair Market Value on the Purchase Date), (iv) reduce the maximum number of shares of Stock that may be purchased in any Offering Period, or (v) take any combination of the foregoing actions.

* * *

As adopted by the Board of Directors of the Company on March 24, 2020, and as adopted by the stockholders of the Company on June 8, 2020, and as amended by the Board of Directors of the Company on April 18, 2023 and adopted by the stockholders of the Company on June 6, 2023, and as further amended by the Committee on April 18, 2024 and adopted by the stockholders of the Company on June 11, 2024, and as further amended by the Board of Directors on April 21, 2025 and adopted by the stockholders of the Company on June 10, 2025.

IOVANCE BIOTHERAPEUTICS, INC.
2018 EQUITY INCENTIVE PLAN AS AMENDED

1. Purpose. The Iovance Biotherapeutics, Inc. 2018 Equity Incentive Plan (as amended from time to time, the "**Plan**") is intended to help Iovance Biotherapeutics, Inc., a Delaware corporation (including any successor thereto, the "**Company**"), and its Affiliates attract and retain key personnel by providing them the opportunity to acquire an equity interest in the Company or other incentive compensation measured by reference to the value of Common Stock and to align the interests of key personnel with those of the Company's stockholders.

2. Effective Date; Duration. The Plan will become effective, if at all, upon the date (the "**Effective Date**") that the Plan is originally approved by the stockholders of the Company. The expiration date of the Plan, on and after which date no Awards may be granted, shall be the tenth anniversary of the Effective Date; provided, however, that such expiration shall not affect Awards then outstanding, and the terms and conditions of the Plan shall continue to apply to such Awards.

3. Definitions. When used herein, the following capitalized terms shall have the meanings indicated, and their plural forms shall have the pluralized forms of their meanings indicated:

(a) "**Affiliate**" means any person or entity that directly or indirectly controls, is controlled by, or is under common control with, the Company. The term "control" (including, with correlative meaning, the terms "controlled by" and "under common control with"), as applied to any person or entity, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such person or entity, whether through the ownership of voting or other securities, by contract or otherwise.

(b) "**Amendment Date**" means, subject to approval by the Company's stockholders of the amendments to the Plan, the date of the Company's 2025 annual meeting of stockholders.

(c) "**Award**" means any Incentive Stock Option, Nonqualified Stock Option, Stock Appreciation Right, Restricted Stock, Restricted Stock Unit, or Other Stock-Based Award granted under the Plan.

(d) "**Award Agreement**" means the agreement (whether in written or electronic form) or other instrument or document evidencing any Award granted under the Plan.

(e) "**Beneficial Ownership**" has the meaning set forth in Rule 13d-3 promulgated under Section 13 of the Exchange Act.

(f) "**Board**" means the Board of Directors of the Company.

(g) "**Cause**" in the case of a particular Award, unless the applicable Award Agreement states otherwise, (i) shall have the meaning given such term (or term of similar import) in any employment, consulting, change-in-control, severance or any other agreement between the Participant and the Company or any of its Affiliates, or severance plan in which the Participant is eligible to participate, in either case in effect at the time of the Participant's

termination of employment or service with the Company and its Affiliates, or (ii) if "cause" (or term of similar import) is not defined in, or in the absence of, any such employment, consulting, change-in-control, severance or any other agreement between the Participant and the Company or any of its Affiliates, or severance plan in which the Participant is eligible to participate, means: (A) the Participant's conviction of, or entry of a plea of no contest to (x) a felony or (y) a misdemeanor involving moral turpitude, (B) the Participant's gross negligence or willful misconduct, or a willful failure to attempt in good faith to substantially perform his or her duties (other than due to physical illness or incapacity), (C) the Participant's material breach of a material provision of any employment agreement, consulting agreement, directorship agreement or similar services agreement or offer letter between the Participant and the Company or any of its Affiliates, or any non-competition, non-disclosure or non-solicitation agreement with the Company or any of its Affiliates, (D) the Participant's material violation of any written policies adopted by the Company or any of its Affiliates governing the conduct of persons performing services on behalf of the Company or any of its Affiliates, (E) the Participant's obtaining any material improper personal benefit as result of breach by the Participant of any covenant or agreement (including a breach by the Participant of the Company's code of ethics or a material breach by the Participant of other written policies furnished to the Participant relating to personal investment transactions) of which the Participant was or should have been aware, (F) the Participant's fraud or misappropriation, embezzlement or material misuse of funds or property belonging to the Company or any of its Affiliates, (G) the Participant's use of alcohol or drugs that materially interferes with the performance of his or her duties, or (H) willful or reckless misconduct in respect of the Participant's obligations to the Company or its Affiliates or other acts of misconduct by the Participant occurring during the course of the Participant's employment or service that in either case results in or could reasonably be expected to result in material damage to the property, business or reputation of the Company or its Affiliates. Notwithstanding anything to the contrary herein, and except where provided otherwise by an applicable agreement, if, within six (6) months following a Participant's termination of employment or service for any reason other than by the Company for Cause, the Company determines that such Participant's termination of employment or service could have been for Cause, such Participant's termination of employment or service will be deemed to have been for Cause for all purposes, and such Participant will be required to disgorge to the Company all amounts received under this Plan, any Award Agreement or otherwise that would not have been payable to such Participant had such termination of employment or service been by the Company for Cause. The determination of whether Cause exists shall be made by the Committee in its sole discretion.

(h) "**Change in Control**" means, in the case of a particular Award, unless the applicable Award Agreement (or any employment, consulting, change-in-control, severance or other agreement between the Participant and the Company or any of its Affiliates) states otherwise, the first to occur of any of the following events:

(i) the acquisition by any Person or related "group" (as such term is used in Section 13(d) and Section 14(d) of the Exchange Act) of Persons, or Persons acting jointly or in concert, of Beneficial Ownership (including control or direction) of 50% or more (on a fully diluted basis) of either (A) the then-outstanding shares of Common Stock, including Common Stock issuable upon the exercise of options or warrants, the conversion of convertible stock or debt, and the exercise of any similar right

to acquire such Common Stock (the "**Outstanding Company Common Stock**"), or (B) the combined voting power of the then-outstanding voting securities of the Company entitled to vote in the election of directors (the "**Outstanding Company Voting Securities**"), but excluding any acquisition by the Company or any of its Affiliates or by any employee benefit plan sponsored or maintained by the Company or any of its Affiliates;

(ii) a change in the composition of the Board such that members of the Board during any consecutive 12-month period (the "**Incumbent Directors**") cease to constitute a majority of the Board. Any person becoming a director through election or nomination for election approved by a valid vote of at least two thirds of the Incumbent Directors shall be deemed an Incumbent Director; provided, however, that no individual becoming a director as a result of an actual or threatened election contest, as such terms are used in Rule 14a-12 of Regulation 14A promulgated under the Exchange Act, or as a result of any other actual or threatened solicitation of proxies or consents by or on behalf of any person other than the Board, shall be deemed an Incumbent Director;

(iii) the approval by the stockholders of the Company of a plan of complete dissolution or liquidation of the Company; and

(iv) the consummation of a reorganization, recapitalization, merger, amalgamation, consolidation, statutory share exchange or similar form of corporate transaction involving the Company (a "**Business Combination**"), or sale, transfer or other disposition of all or substantially all of the business or assets of the Company to an entity that is not an Affiliate of the Company (a "**Sale**"), unless immediately following such Business Combination or Sale: (A) more than 50% of the total voting power of the entity resulting from such Business Combination or the entity that acquired all or substantially all of the business or assets of the Company in such Sale (in either case, the "**Surviving Company**"), or the ultimate parent entity that has Beneficial Ownership of sufficient voting power to elect a majority of the board of directors (or analogous governing body) of the Surviving Company (the "**Parent Company**"), is represented by the Outstanding Company Voting Securities that were outstanding immediately prior to such Business Combination or Sale (or, if applicable, is represented by shares into which the Outstanding Company Voting Securities were converted pursuant to such Business Combination or Sale), and such voting power among the holders thereof is in substantially the same proportion as the voting power of the Outstanding Company Voting Securities among the holders thereof immediately prior to the Business Combination or Sale, (B) no Person (other than any employee benefit plan sponsored or maintained by the Surviving Company or the Parent Company) is or becomes the beneficial owner, directly or indirectly, of 50% or more of the total voting power of the outstanding voting securities eligible to elect members of the board of directors (or the analogous governing body) of the Parent Company (or, if there is no Parent Company, the Surviving Company), and (C) at least a majority of the members of the board of directors (or the analogous governing body) of the Parent Company (or, if there is no Parent Company, the Surviving Company) following the consummation of the Business Combination or Sale were Board members at the time of the Board's approval of the execution of the initial agreement providing for such Business Combination or Sale.

(i) "**Code**" means the U.S. Internal Revenue Code of 1986, as amended, and any successor thereto. References to any section of the Code shall be deemed to include any regulations or other interpretative guidance under such section, and any amendments or successors thereto.

(j) "**Committee**" means the Compensation Committee of the Board or a subcommittee thereof if required with respect to actions taken to comply with Rule 16b-3 promulgated under the Exchange Act in respect of Awards or, if no such Compensation Committee or subcommittee thereof exists, or if the Board otherwise takes action hereunder on behalf of the Committee, the Board.

(k) "**Common Stock**" means the common stock of the Company, par value $0.000041666 per share (and any stock or other securities into which such common stock may be converted or into which it may be exchanged).

(l) "**Disability**" means cause for termination of the Participant's employment or service due to a determination that the Participant is disabled in accordance with a long-term disability insurance program maintained by the Company or a determination by the U.S. Social Security Administration that the Participant is totally disabled.

(m) **"$"** shall refer to the United States dollars.

(n) "**Eligible Director**" means a director who satisfies the conditions set forth in Section 4(a) of the Plan.

(o) "**Eligible Person**" means any (i) individual employed by the Company or a Subsidiary; provided, however, that no such employee covered by a collective bargaining agreement shall be an Eligible Person, (ii) director or officer of the Company or a Subsidiary, (iii) consultant or advisor to the Company or an Affiliate who may be offered securities registrable on Form S-8 under the Securities Act, or (iv) prospective employee, director, officer, consultant or advisor who has accepted an offer of employment or service from the Company or its Subsidiaries (and would satisfy the provisions of clause (i), (ii) or (iii) above once such individual begins employment with or providing services to the Company or a Subsidiary).

(p) "**Exchange Act**" means the U.S. Securities Exchange Act of 1934, as amended, and any successor thereto. References to any section of (or rule promulgated under) the Exchange Act shall be deemed to include any rules, regulations or other interpretative guidance under such section or rule, and any amendments or successors thereto.

(q) "**Exercise Price**" has the meaning set forth in Section 7(b) of the Plan.

(r) "**Fair Market Value**" means, (i) with respect to Common Stock on a given date, (x) if the Common Stock is listed on a national securities exchange, the closing sales price of a share of Common Stock reported on such exchange on such date, or if there is no such sale on that date, then on the last preceding date on which such a sale was reported, or (y) if the Common Stock is not listed on any national securities exchange, the amount determined by the Committee in good faith to be the fair market value of the Common Stock, or (ii) with respect to

any other property on any given date, the amount determined by the Committee in good faith to be the fair market value of such other property as of such date.

(s) "**Incentive Stock Option**" means an Option that is designated by the Committee as an incentive stock option as described in Section 422 of the Code and otherwise meets the requirements set forth in the Plan.

(t) "**Immediate Family Members**" has the meaning set forth in Section 14(b)(ii) of the Plan.

(u) "**Indemnifiable Person**" has the meaning set forth in Section 4(e) of the Plan.

(v) "**NASDAQ**" means The NASDAQ Stock Market.

(w) "**Nonqualified Stock Option**" means an Option that is not designated by the Committee as an Incentive Stock Option.

(x) "**Option**" means an Award granted under Section 7 of the Plan.

(y) "**Option Period**" has the meaning set forth in Section 7(c) of the Plan.

(z) "**Other Stock-Based Award**" means an Award granted under Section 10 of the Plan.

(aa) "**Participant**" has the meaning set forth in Section 6 of the Plan.

(bb) "**Permitted Transferee**" has the meaning set forth in Section 14(b)(ii) of the Plan.

(cc) "**Person**" has the meaning given in Section 3(a)(9) of the Exchange Act, as modified and used in Sections 13(d) and 14(d) thereof, except that such term shall not include (i) the Company or any of its Subsidiaries, (ii) a trustee or other fiduciary holding securities under an employee benefit plan of the Company or any of its Affiliates, (iii) an underwriter temporarily holding securities pursuant to an offering of such securities, or (iv) a corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of Common Stock of the Company.

(dd) "**Prior Award**" means any incentive stock option, nonqualified stock option, stock appreciation right, or restricted stock granted under the Prior Plan.

(ee) "**Prior Plan**" means the Lion Biotechnologies, Inc. 2014 Equity Incentive Plan, as amended.

(ff) "**Prior Plan Shares**" means the number of shares of Common Stock available for issuance under the Prior Plan on the Amendment Date.

(gg) "**Released Unit**" has the meaning set forth in Section 9(d)(ii) of the Plan.

(hh) "**Restricted Period**" has the meaning set forth in Section 9(a) of the Plan.

(ii) "**Restricted Stock**" means an Award of Common Stock, subject to certain specified restrictions, granted under Section 9 of the Plan.

(jj) "**Restricted Stock Unit**" means an Award of an unfunded and unsecured promise to deliver shares of Common Stock, cash, other securities or other property, subject to certain specified restrictions, granted under Section 9 of the Plan.

(kk) "**SAR Period**" has the meaning set forth in Section 8(c) of the Plan.

(ll) "**Securities Act**" means the U.S. Securities Act of 1933, as amended, and any successor thereto. Reference in the Plan to any section of (or rule promulgated under) the Securities Act shall be deemed to include any rules, regulations or other interpretative guidance under such section or rule, and any amendments or successor provisions to such section, rules, regulations or other interpretive guidance.

(mm) "**Strike Price**" has the meaning set forth in Section 8(b) of the Plan.

(nn) "**Stock Appreciation Right**" or "SAR" means an Award granted under Section 8 of the Plan.

(oo) "**Subsidiary**" means any corporation or other entity a majority of whose outstanding voting stock or voting power is beneficially owned directly or indirectly by the Company.

(pp) "**Substitute Awards**" has the meaning set forth in Section 5(e) of the Plan.

4. Administration.

(a) The Plan shall be administered by the Committee or, in the Board's sole discretion, by the Board. Subject to the terms of the Plan, the Committee (or the Board) shall have the sole and plenary authority to (i) designate Participants, (ii) determine the type, size, and terms and conditions of Awards to be granted and to grant such Awards, (iii) determine the method by which an Award may be settled, exercised, canceled, forfeited, suspended, or repurchased by the Company, (iv) determine the circumstances under which the delivery of cash, property or other amounts payable with respect to an Award may be deferred, either automatically or at the Participant's or Committee's election, (v) interpret, administer, reconcile any inconsistency in, correct any defect in and supply any omission in the Plan and any Award granted under the Plan, (vi) establish, amend, suspend, or waive any rules and regulations and appoint such agents as the Committee shall deem appropriate for the proper administration of the Plan, (vii) accelerate the vesting, delivery or exercisability of, or payment for or lapse of restrictions on, or waive any condition in respect of, Awards, and (viii) make any other determination and take any other action that the Committee deems necessary or desirable for the administration of the Plan or to comply with any applicable law. To the extent required to comply with the provisions of Rule 16b-3 promulgated under the Exchange Act (if applicable and if the Board is not acting as the Committee under the Plan), or any exception or exemption

under applicable securities laws or the applicable NASDAQ rules or the rules of any other securities exchange or inter-dealer quotation service on which the Common Stock is listed or quoted, as applicable, it is intended that each member of the Committee shall, at the time such member takes any action with respect to an Award under the Plan, be (1) a "non-employee director" within the meaning of Rule 16b-3 promulgated under the Exchange Act or (2) an "independent director" under NASDAQ rules or the rules of any other securities exchange or inter-dealer quotation service on which the Common Stock is listed or quoted, or a person meeting any similar requirement under any successor rule or regulation ("**Eligible Director**"). However, the fact that a Committee member shall fail to qualify as an Eligible Director shall not invalidate any Award granted or action taken by the Committee that is otherwise validly granted or taken under the Plan.

(b) The Committee may delegate all or any portion of its responsibilities and powers to any persons selected by it, except for grants of Awards to persons who are non-employee members of the Board or are otherwise subject to Section 16 of the Exchange Act. Any such delegation may be revoked by the Committee at any time.

(c) As further set forth in Section 14(f) of the Plan, the Committee shall have the authority to amend the Plan and Awards to the extent necessary to permit participation in the Plan by Eligible Persons who are located outside of the United States on terms and conditions comparable to those afforded to Eligible Persons located within the United States; provided, however, that no such action shall be taken without stockholder approval if such approval is required by applicable securities laws or regulation or NASDAQ rules or the rules of any other securities exchange or inter-dealer quotation service on which the Common Stock is listed or quoted.

(d) Unless otherwise expressly provided in the Plan, all designations, determinations, interpretations, and other decisions regarding the Plan or any Award or any documents evidencing Awards granted pursuant to the Plan shall be within the sole discretion of the Committee, may be made at any time and shall be final, conclusive and binding upon all persons and entities, including, without limitation, the Company, any Affiliate, any Participant, any holder or beneficiary of any Award, and any stockholder of the Company.

(e) No member of the Board or the Committee, nor any employee or agent of the Company (each such person, an "**Indemnifiable Person**"), shall be liable for any action taken or omitted to be taken or any determination made with respect to the Plan or any Award hereunder (unless constituting fraud or a willful criminal act or willful criminal omission). Each Indemnifiable Person shall be indemnified and held harmless by the Company against and from any loss, cost, liability, or expense (including attorneys' fees) that may be imposed upon or incurred by such Indemnifiable Person in connection with or resulting from any action, suit or proceeding to which such Indemnifiable Person may be involved as a party, witness or otherwise by reason of any action taken or omitted to be taken or determination made under the Plan or any Award Agreement and against and from any and all amounts paid by such Indemnifiable Person with the Company's approval (not to be unreasonably withheld), in settlement thereof, or paid by such Indemnifiable Person in satisfaction of any judgment in any such action, suit or proceeding against such Indemnifiable Person, and the Company shall advance to such Indemnifiable Person any such expenses promptly upon written request (which request shall include an undertaking by

the Indemnifiable Person to repay the amount of such advance if it shall ultimately be determined as provided below that the Indemnifiable Person is not entitled to be indemnified); provided, that the Company shall have the right, at its own expense, to assume and defend any such action, suit or proceeding, and once the Company gives notice of its intent to assume the defense, the Company shall have sole control over such defense with counsel of recognized standing of the Company's choice. The foregoing right of indemnification shall not be available to an Indemnifiable Person to the extent that a final judgment or other final adjudication (in either case not subject to further appeal) binding upon such Indemnifiable Person determines that the acts or omissions or determinations of such Indemnifiable Person giving rise to the indemnification claim resulted from such Indemnifiable Person's fraud or willful criminal act or willful criminal omission or that such right of indemnification is otherwise prohibited by law or by the Company's certificate of incorporation or by-laws. The foregoing right of indemnification shall not be exclusive of or otherwise supersede any other rights of indemnification to which such Indemnifiable Persons may be entitled under the Company's certificate of incorporation or by-laws, as a matter of law, individual indemnification agreement or contract or otherwise, or any other power that the Company may have to indemnify such Indemnifiable Persons or hold them harmless.

(f) The Board may at any time and from time to time grant Awards and administer the Plan with respect to such Awards. In any such case, the Board shall have all the authority granted to the Committee under the Plan.

5. Grant of Awards; Shares Subject to the Plan; Limitations.

(a) Awards. The Committee may grant Awards to one or more Eligible Persons.

(b) Share Limits. Subject to Section 11 of the Plan and subsection (e): the number of shares of Common Stock that may be reserved for issuance and delivered in the aggregate pursuant to Awards granted under the Plan shall be equal to (i) 49,200,000 shares of Common Stock plus (ii) the Prior Plan Shares (the "**Share Pool**"). No more than 49,503,563 shares of Common Stock may be delivered pursuant to the exercise of Incentive Stock Options granted under the Plan. The maximum number of Awards that may be granted in any single fiscal year to each of the non-employee members of the Board for serving on the Board, shall be an amount equal to the grant date fair value of $425,000 computed in accordance with Financial Accounting Standards Board ("**FASB**") Accounting Standards Codification ("**ASC**") Topic 718, "Compensation — Stock Compensation," disregarding the estimate of forfeitures; provided, that the foregoing limitation shall not apply in respect of any Awards issued to a non- employee director in respect of (i) any one-time equity grant upon a non-employee director's initial appointment or election to the Board, (ii) equity grants for services provided to the Company other than services as a member of the Board, (iii) any additional compensation directors may receive for chair or committee service, or (iv) any special one-time equity grants or other special one-time compensation awarded to one or more non-employee directors to reward such directors for an extraordinary achievement by the Company. The total amount of Awards granted annually to the non-employee members of the Board may allocated amongst the non-employee members of the Board in a manner determined by the Board.

(c) Share Counting. The Share Pool shall be reduced, on the date of grant, by the relevant number of shares of Common Stock for each Award granted under the Plan that is valued by reference to a share of Common Stock; provided that Awards that are valued by reference to shares of Common Stock but are required to be paid in cash pursuant to their terms shall not reduce the Share Pool. If and to the extent that Awards originating from the Share Pool, or Prior Awards following the Effective Date, terminate, expire, or are canceled, forfeited, exchanged, or surrendered without having been exercised, vested, or settled, the shares of Common Stock subject to such Awards or Prior Awards shall again be available for Awards under the Share Pool. Notwithstanding the foregoing, the following shares of Common Stock shall not become available for issuance under the Plan: (i) shares of Common Stock tendered by Participants, or withheld by the Company, as full or partial payment to the Company upon the exercise of Stock Options granted under the Plan; (ii) shares of Common Stock reserved for issuance upon the grant of Stock Appreciation Rights, to the extent that the number of reserved shares of Common Stock exceeds the number of shares of Common Stock actually issued upon the exercise of the Stock Appreciation Rights; and (iii) shares of Common Stock withheld by, or otherwise remitted to, the Company to satisfy a Participant's tax withholding obligations upon the lapse of restrictions on, settlement of, or exercise of Awards granted under the Plan.

(d) Source of Shares. Shares of Common Stock delivered by the Company in settlement of Awards may be authorized and unissued shares, shares held in the treasury of the Company, shares purchased on the open market or by private purchase, or a combination of the foregoing.

(e) Substitute Awards. The Committee may grant Awards in assumption of, or in substitution for, outstanding awards previously granted by the Company or any Affiliate or an entity directly or indirectly acquired by the Company or with which the Company combines ("**Substitute Awards**"), and such Substitute Awards shall not be counted against the aggregate number of shares of Common Stock available for Awards; provided, that Substitute Awards issued or intended as "incentive stock options" within the meaning of Section 422 of the Code shall be counted against the aggregate number of Incentive Stock Options available under the Plan.

(f) No Further Awards Under Prior Plan. Effective as of the Amendment Date, no further awards shall be made under the Prior Plan, but all Prior Awards which are outstanding as of such date shall continue to be governed by the terms, conditions and procedures set forth in the Prior Plan and any applicable agreement (whether in written or electronic form) or other instrument or document evidencing any award granted under the Prior Plan.

6. Eligibility. Participation shall be limited to Eligible Persons who have been selected by the Committee and who have entered into an Award Agreement with respect to an Award granted to them under the Plan (each such Eligible Person, a "**Participant**").

7. Options.

(a) Generally. Each Option shall be subject to the conditions set forth in the Plan and in the applicable Award Agreement. All Options granted under the Plan shall be

Nonqualified Stock Options unless the Award Agreement expressly states otherwise. Incentive Stock Options shall be granted only subject to and in compliance with Section 422 of the Code, and only to Eligible Persons who are employees of the Company or of a parent or subsidiary of the Company (within the meaning of Sections 424(e) and 424(f) of the Code). If for any reason an Option intended to be an Incentive Stock Option (or any portion thereof) shall not qualify as an Incentive Stock Option, then, to the extent of such nonqualification, such Option or portion thereof shall be regarded as a Nonqualified Stock Option properly granted under the Plan.

(b) Exercise Price. The exercise price ("**Exercise Price**") per share of Common Stock for each Option (that is not a Substitute Award) shall not be less than 100% of the Fair Market Value of such share, determined as of the date of grant. Any modification to the Exercise Price of an outstanding Option shall be subject to the prohibition on repricing set forth in Section 13(b).

(c) Vesting, Exercise and Expiration. The Committee shall determine the manner and timing of vesting, exercise and expiration of Options. The period between the date of grant and the scheduled expiration date of the Option ("**Option Period**") shall not exceed ten years, unless the Option Period (other than in the case of an Incentive Stock Option) would expire at a time when trading in the shares of Common Stock is prohibited by the Company's insider-trading policy or a Company-imposed "blackout period," in which case the Option Period shall be extended automatically until the 30th day following the expiration of such prohibition (so long as such extension shall not violate Section 409A of the Code). The Committee may accelerate the vesting and/or exercisability of any Option, which acceleration shall not affect any other terms and conditions of such Option.

(d) Method of Exercise and Form of Payment. No shares of Common Stock shall be delivered pursuant to any exercise of an Option until the Participant has paid the Exercise Price to the Company in full, and an amount equal to any U.S. federal, state and local income and employment taxes and non-U.S. income and employment taxes, social contributions and any other tax-related items required to be withheld. Options may be exercised by delivery of written or electronic notice of exercise to the Company or its designee (including a third-party administrator) in accordance with the terms of the Option and the Award Agreement accompanied by payment of the Exercise Price and such applicable taxes. The Exercise Price and delivery of all applicable required withholding taxes shall be payable (i) in cash, by check or cash equivalent, or (ii) by such other method as elected by the Participant and that the Committee may permit, in its sole discretion, including without limitation: (A) shares of Common Stock valued at the Fair Market Value at the time the Option is exercised (including, pursuant to procedures approved by the Committee, by means of attestation of ownership of a sufficient number of shares of Common Stock in lieu of actual delivery of such shares to the Company) or any combination of the foregoing; provided, that such shares of Common Stock are not subject to any pledge or other security interest; (B) in the form of other property having a Fair Market Value on the date of exercise equal to the Exercise Price and all applicable required withholding taxes; (C) if there is a public market for the shares of Common Stock at such time, by means of a broker-assisted "cashless exercise" pursuant to which the Company or its designee (including third-party administrators) is delivered a copy of irrevocable instructions to a stockbroker to sell the shares of Common Stock otherwise deliverable upon the exercise of the Option and to deliver promptly to the Company an amount equal to the Exercise Price and all applicable required

withholding taxes against delivery of the shares of Common Stock to settle the applicable trade; or (D) by means of a "net exercise" procedure effected by withholding the minimum number of shares of Common Stock otherwise deliverable in respect of an Option that are needed to pay for the Exercise Price and up to the maximum required withholding taxes. In all events of cashless or net exercise, any fractional shares of Common Stock shall be settled in cash.

(e) Notification upon Disqualifying Disposition of an Incentive Stock Option. Each Participant awarded an Incentive Stock Option under the Plan shall notify the Company in writing immediately after the date on which the Participant makes a disqualifying disposition of any Common Stock acquired pursuant to the exercise of such Incentive Stock Option. A disqualifying disposition is any disposition (including, without limitation, any sale) of such Common Stock before the later of (i) two years after the date of grant of the Incentive Stock Option and (ii) one year after the date of exercise of the Incentive Stock Option. The Company may, if determined by the Committee and in accordance with procedures established by the Committee, retain possession, as agent for the applicable Participant, of any Common Stock acquired pursuant to the exercise of an Incentive Stock Option until the end of the period described in the preceding sentence, subject to complying with any instruction from such Participant as to the sale of such Common Stock.

(f) Compliance with Laws. Notwithstanding the foregoing, in no event shall the Participant be permitted to exercise an Option in a manner that the Committee determines would violate the Sarbanes-Oxley Act of 2002, or any other applicable law or the applicable rules and regulations of the Securities and Exchange Commission or the applicable rules and regulations of any securities exchange or inter-dealer quotation service on which the Common Stock of the Company is listed or quoted.

(g) Incentive Stock Option Grants to 10% Stockholders. Notwithstanding anything to the contrary in this Section 7, if an Incentive Stock Option is granted to a Participant who owns stock representing more than ten percent of the voting power of all classes of stock of the Company or of a parent or subsidiary of the Company (within the meaning of Sections 424(e) and 424(f) of the Code), the Option Period shall not exceed five years from the date of grant of such Option and the Exercise Price shall be at least 110% of the Fair Market Value (on the date of grant) of the shares subject to the Option.

(h) $100,000 Per Year Limitation for Incentive Stock Options. To the extent that the aggregate Fair Market Value (determined as of the date of grant) of shares of Common Stock for which Incentive Stock Options are exercisable for the first time by any Participant during any calendar year (under all plans of the Company) exceeds $100,000, such excess Incentive Stock Options shall be treated as Nonqualified Stock Options.

8. Stock Appreciation Rights (SARs).

(a) Generally. Each SAR shall be subject to the conditions set forth in the Plan and the Award Agreement. Any Option granted under the Plan may include a tandem SAR. The Committee also may award SARs independent of any Option.

(b) Strike Price. The strike price ("**Strike Price**") per share of Common Stock for each SAR shall not be less than 100% of the Fair Market Value of such share, determined as

of the date of grant; provided, however, that a SAR granted in tandem with (or in substitution for) an Option previously granted shall have a Strike Price equal to the Exercise Price of the corresponding Option. Any modification to the Strike Price of an outstanding SAR shall be subject to the prohibition on repricing set forth in Section 13(b).

(c) Vesting and Expiration. A SAR granted in tandem with an Option shall vest and become exercisable and shall expire according to the same vesting schedule and expiration provisions as the corresponding Option. A SAR granted independently of an Option shall vest and become exercisable and shall expire in such manner and on such date or dates determined by the Committee and shall expire after such period, not to exceed ten years, as may be determined by the Committee (the "**SAR Period**"); provided, however, that notwithstanding any vesting or exercisability dates set by the Committee, the Committee may accelerate the vesting and/or exercisability of any SAR, which acceleration shall not affect the terms and conditions of such SAR other than with respect to vesting and/or exercisability. If the SAR Period would expire at a time when trading in the shares of Common Stock is prohibited by the Company's insider trading policy or a Company-imposed "blackout period," the SAR Period shall be automatically extended until the 30th day following the expiration of such prohibition (so long as such extension shall not violate Section 409A of the Code).

(d) Method of Exercise. SARs may be exercised by delivery of written or electronic notice of exercise to the Company or its designee (including a third-party administrator) in accordance with the terms of the Award, specifying the number of SARs to be exercised and the date on which such SARs were awarded.

(e) Payment. Upon the exercise of a SAR, the Company shall pay to the holder thereof an amount equal to the number of shares subject to the SAR that are being exercised multiplied by the excess, if any, of the Fair Market Value of one share of Common Stock on the exercise date over the Strike Price, less an amount equal to any U.S. federal, state and local income and employment taxes and non-U.S. income and employment taxes, social contributions and any other tax-related items required to be withheld. The Company shall pay such amount in cash, in shares of Common Stock valued at Fair Market Value as determined on the date of exercise, or any combination thereof, as determined by the Committee. Any fractional shares of Common Stock shall be settled in cash.

9. Restricted Stock and Restricted Stock Units.

(a) Generally. Each Restricted Stock and Restricted Stock Unit Award shall be subject to the conditions set forth in the Plan and the applicable Award Agreement. The Committee shall establish restrictions applicable to Restricted Stock and Restricted Stock Units, including the period over which the restrictions shall apply (the "**Restricted Period**"), and the time or times at which Restricted Stock or Restricted Stock Units shall become vested (which, for the avoidance of doubt, may include service- and/or performance-based vesting conditions). Subject to such rules, approvals, and conditions as the Committee may impose from time to time, an Eligible Person who is a non-employee director may elect to receive all or a portion of such Eligible Person's cash director fees and other cash director compensation payable for director services provided to the Company by such Eligible Person in any fiscal year, in whole or in part, in the form of Restricted Stock Units. The Committee may accelerate the vesting and/or the lapse

of any or all of the restrictions on Restricted Stock and Restricted Stock Units which acceleration shall not affect any other terms and conditions of such Awards. No share of Common Stock shall be issued at the time an Award of Restricted Stock Units is made, and the Company will not be required to set aside a fund for the payment of any such Award.

(b) Stock Certificates; Escrow or Similar Arrangement. Upon the grant of Restricted Stock, the Committee shall cause share(s) of Common Stock to be registered in the name of the Participant and held in book-entry form subject to the Company's directions. The Committee may also cause a stock certificate registered in the name of the Participant to be issued. In such event, the Committee may provide that such certificates shall be held by the Company or in escrow rather than delivered to the Participant pending vesting and release of restrictions, in which case the Committee may require the Participant to execute and deliver to the Company or its designee (including third-party administrators) (i) an escrow agreement satisfactory to the Committee, if applicable, and (ii) the appropriate stock power (endorsed in blank) with respect to the Restricted Stock. If the Participant shall fail to execute and deliver the escrow agreement and blank stock power within the amount of time specified by the Committee, the Award shall be null and void. Subject to the restrictions set forth in this Section 9 and the Award Agreement, the Participant shall have the rights and privileges of a stockholder as to such Restricted Stock, including without limitation the right to vote such Restricted Stock.

(c) Restrictions; Forfeiture. Restricted Stock and Restricted Stock Units awarded to the Participant shall be subject to forfeiture until the expiration of the Restricted Period and the attainment of any other vesting criteria established by the Committee, and shall be subject to the restrictions on transferability set forth in the Award Agreement. In the event of any forfeiture, all rights of the Participant to such Restricted Stock (or as a stockholder with respect thereto), and to such Restricted Stock Units, as applicable, including to any dividends and/or dividend equivalents that may have been accumulated and withheld during the Restricted Period in respect thereof, shall terminate without further action or obligation on the part of the Company. The Committee shall have the authority to remove any or all of the restrictions on the Restricted Stock and Restricted Stock Units whenever it may determine that, by reason of changes in applicable laws or other changes in circumstances arising after the date of grant of the Restricted Stock Award or Restricted Stock Unit Award, such action is appropriate.

(d) Delivery of Restricted Stock and Settlement of Restricted Stock Units.

(i) Upon the expiration of the Restricted Period with respect to any shares of Restricted Stock and the attainment of any other vesting criteria, the restrictions set forth in the applicable Award Agreement shall be of no further force or effect, except as set forth in the Award Agreement. If an escrow arrangement is used, upon such expiration the Company shall deliver to the Participant or such Participant's beneficiary (via book-entry notation or, if applicable, in stock certificate form) the shares of Restricted Stock with respect to which the Restricted Period has expired (rounded down to the nearest full share). Dividends, if any, that may have been withheld by the Committee and attributable to the Restricted Stock shall be distributed to the Participant in cash or in shares of Common Stock having a Fair Market Value (on the date of distribution) (or a combination of cash and shares of Common Stock) equal to the amount of such dividends, upon the release of restrictions on the Restricted Stock.

(ii) Unless otherwise provided by the Committee in an Award Agreement, upon the expiration of the Restricted Period and the attainment of any other vesting criteria established by the Committee, with respect to any outstanding Restricted Stock Units, the Company shall deliver to the Participant, or such Participant's beneficiary (via book-entry notation or, if applicable, in stock certificate form), one share of Common Stock (or other securities or other property, as applicable) for each such outstanding Restricted Stock Unit that has not then been forfeited and with respect to which the Restricted Period has expired and any other such vesting criteria are attained ("**Released Unit**"); provided, however, that the Committee may elect to (A) pay cash or part cash and part Common Stock in lieu of delivering only shares of Common Stock in respect of such Released Units or (B) establish a program for deferred delivery of Common Stock (or cash or part Common Stock and part cash, as the case may be) beyond the expiration of the Restricted Period in compliance with Section 409A of the Code. If a cash payment is made in lieu of delivering shares of Common Stock, the amount of such payment shall be equal to the Fair Market Value of the Common Stock as of the date on which the shares of Common Stock would have otherwise been delivered to the Participant in respect of such Restricted Stock Units.

(iii) To the extent provided in an Award Agreement, the holder of outstanding Restricted Stock Units shall be entitled to be credited with dividend equivalent payments (upon the payment by the Company of dividends on shares of Common Stock) either in cash or, if determined by the Committee, in shares of Common Stock having a Fair Market Value equal to the amount of such dividends as of the date of payment (or a combination of cash and shares of Common Stock) (and interest may, if determined by the Committee, be credited on the amount of cash dividend equivalents at a rate and subject to such terms as determined by the Committee), which accumulated dividend equivalents (and interest thereon, if applicable) shall be payable at the same time as the underlying Restricted Stock Units are settled (in the case of Restricted Stock Units, following the release of restrictions on such Restricted Stock Units), and if such Restricted Stock Units are forfeited, the holder thereof shall have no right to such dividend equivalent payments.

(e) Legends on Restricted Stock. Each certificate representing Restricted Stock awarded under the Plan, if any, shall bear a legend substantially in the form of the following in addition to any other information the Company deems appropriate until the lapse of all restrictions with respect to such Common Stock:

TRANSFER OF THIS CERTIFICATE AND THE SHARES REPRESENTED HEREBY IS RESTRICTED PURSUANT TO THE TERMS OF THE IOVANCE BIOTHERAPEUTICS, INC. 2018 EQUITY INCENTIVE PLAN AND A RESTRICTED STOCK AWARD AGREEMENT, DATED AS OF ___, BETWEEN IOVANCE BIOTHERAPEUTICS, INC. AND ___. A COPY OF SUCH PLAN AND AWARD AGREEMENT IS ON FILE AT THE PRINCIPAL EXECUTIVE OFFICES OF IOVANCE BIOTHERAPEUTICS, INC.

10. Other Stock-Based Awards. The Committee may issue unrestricted Common Stock, rights to receive future grants of Awards, or other Awards denominated in Common Stock (including performance shares or performance units), or Awards that provide for cash payments

based in whole or in part on the value or future value of shares of Common Stock under the Plan to Eligible Persons, alone or in tandem with other Awards, in such amounts as the Committee shall from time to time determine ("**Other Stock-Based Awards**"). Each Other Stock-Based Award shall be evidenced by an Award Agreement, which may include conditions including, without limitation, the payment by the Participant of the Fair Market Value of such shares of Common Stock on the date of grant.

11. Changes in Capital Structure and Similar Events. In the event of (a) any dividend (other than regular cash dividends) or other distribution (whether in the form of cash, shares of Common Stock, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, amalgamation, consolidation, split-up, split-off, spin-off, combination, repurchase or exchange of shares of Common Stock or other securities of the Company, issuance of warrants or other rights to acquire shares of Common Stock or other securities of the Company, or other similar corporate transaction or event (including, without limitation, a Change in Control) that affects the shares of Common Stock, or (b) unusual or nonrecurring events (including, without limitation, a Change in Control) affecting the Company, any Affiliate, or the financial statements of the Company or any Affiliate, or changes in applicable rules, rulings, regulations or other requirements of any governmental body or securities exchange or inter-dealer quotation service, accounting principles or law, such that in any case an adjustment is determined by the Committee to be necessary or appropriate, then the Committee shall make any such adjustments in such manner as it may deem equitable, including without limitation any or all of the following:

(i) adjusting any or all of (A) the number of shares of Common Stock or other securities of the Company (or number and kind of other securities or other property) that may be delivered in respect of Awards or with respect to which Awards may be granted under the Plan (including, without limitation, adjusting any or all of the limitations under Section 5 of the Plan) and (B) the terms of any outstanding Award, including, without limitation, (1) the number of shares of Common Stock or other securities of the Company (or number and kind of other securities or other property) subject to outstanding Awards or to which outstanding Awards relate, (2) the Exercise Price or Strike Price with respect to any Award and/or (3) any applicable performance measures;

(ii) providing for a substitution or assumption of Awards (or awards of an acquiring company), accelerating the delivery, vesting and/or exercisability of, lapse of restrictions and/or other conditions on, or termination of, Awards or providing for a period of time (which shall not be required to be more than ten (10) days) for Participants to exercise outstanding Awards prior to the occurrence of such event (and any such Award not so exercised shall terminate or become no longer exercisable upon the occurrence of such event); and

(iii) cancelling any one or more outstanding Awards (or awards of an acquiring company) and causing to be paid to the holders thereof, in cash, shares of Common Stock, other securities or other property, or any combination thereof, the value of such Awards, if any, as determined by the Committee (which if applicable may be based upon the price per share of Common Stock received or to be received by other

stockholders of the Company in such event), including without limitation, in the case of an outstanding Option or SAR, a cash payment in an amount equal to the excess, if any, of the Fair Market Value (as of a date specified by the Committee) of the shares of Common Stock subject to such Option or SAR over the aggregate Exercise Price or Strike Price of such Option or SAR, respectively (it being understood that, in such event, any Option or SAR having a per-share Exercise Price or Strike Price equal to, or in excess of, the Fair Market Value (as of the date specified by the Committee) of a share of Common Stock subject thereto may be canceled and terminated without any payment or consideration therefor);

provided, however, that the Committee shall make an equitable or proportionate adjustment to outstanding Awards to reflect any "equity restructuring" (within the meaning of the Financial Accounting Standards Codification Topic 718 (or any successor pronouncement thereto)). Except as otherwise determined by the Committee, any adjustment in Incentive Stock Options under this Section 11 (other than any cancellation of Incentive Stock Options) shall be made only to the extent not constituting a "modification" within the meaning of Section 424(h)(3) of the Code, and any adjustments under this Section 11 shall be made in a manner that does not adversely affect the exemption provided pursuant to Rule16b-3 promulgated under the Exchange Act. The Company shall give each Participant notice of an adjustment hereunder and, upon notice, such adjustment shall be conclusive and binding for all purposes. In anticipation of the occurrence of any event listed in the first sentence of this Section 11, for reasons of administrative convenience, the Committee in its sole discretion may refuse to permit the exercise of any Award during a period of up to 30 days prior to, and/or up to 30 days after, the anticipated occurrence of any such event.

12. Effect of Change in Control. Except to the extent otherwise provided in an Award Agreement, or any applicable employment, consulting, change-in-control, severance or other agreement between the Participant and the Company or an Affiliate, in the event of a Change in Control, notwithstanding any provision of the Plan to the contrary:

(a) If the Participant's employment with or service to the Company or an Affiliate is terminated by the Company or Affiliate without Cause (and other than due to death or Disability) on or within 12 months following a Change in Control, all Options and SARs held by such Participant shall automatically become immediately exercisable with respect to 100% of the shares subject to such Options and SARs, and that the Restricted Period (and any other conditions) shall expire immediately with respect to 100% of the shares of Restricted Stock and Restricted Stock Units and any other Awards held by such Participant (including a waiver of any applicable performance goals); provided, that if the vesting or exercisability of any Award would otherwise be subject to the achievement of performance conditions, the portion of such Award that shall become fully vested and immediately exercisable shall be based on the assumed achievement of actual or target performance as determined by the Committee and, unless otherwise determined by the Committee, prorated for the number of days elapsed from the grant date of such Award through the date of termination.

(b) In addition, the Committee may upon at least ten (10) days' advance notice to the affected Participants, cancel any outstanding Award and pay to the holders thereof, in cash, securities or other property (including of the acquiring or successor company), or any

combination thereof, the value of such Awards based upon the price per share of Common Stock received or to be received by other stockholders of the Company in the event (it being understood that any Option or SAR having a per-share Exercise Price or Strike Price equal to, or in excess of, the Fair Market Value (as of the date specified by the Committee) of a share of Common Stock subject thereto may be canceled and terminated without any payment or consideration therefor). Notwithstanding the above, the Committee shall exercise such discretion over the timing of settlement of any Award subject to Code Section 409A at the time such Award is granted.

To the extent practicable, the provisions of this Section 12 shall occur in a manner and at a time that allows affected Participants the ability to participate in the Change in Control transaction with respect to the Common Stock subject to their Awards.

13. Amendments and Termination.

(a) Amendment and Termination of the Plan. The Board may amend, alter, suspend, discontinue, or terminate the Plan or any portion thereof at any time; provided, that no such amendment, alteration, suspension, discontinuation or termination shall be made without stockholder approval if such approval is necessary to comply with any tax or regulatory requirement applicable to the Plan (including, without limitation, as necessary to comply with any applicable rules or requirements of NASDAQ or of any other securities exchange or inter-dealer quotation service on which the shares of Common Stock is listed or quoted, for changes in GAAP to new accounting standards); and provided, further, that any such amendment, alteration, suspension, discontinuance or termination that would materially and adversely affect the rights of any Participant or any holder or beneficiary of any Award theretofore granted shall not to that extent be effective without the consent of the affected Participant, holder or beneficiary, unless the Committee determines that such amendment, alteration, suspension, discontinuance or termination is either required or advisable in order for the Company, the Plan or the Award to satisfy any applicable law or regulation. Notwithstanding the foregoing, no amendment shall be made to the last proviso of Section 13(b) without stockholder approval.

(b) Amendment of Award Agreements. The Committee may, to the extent not inconsistent with the terms of any applicable Award Agreement or the Plan, waive any conditions or rights under, amend any terms of, or alter, suspend, discontinue, cancel or terminate, any Award theretofore granted or the associated Award Agreement, prospectively or retroactively (including after the Participant's termination of employment or service with the Company); provided, that any such waiver, amendment, alteration, suspension, discontinuance, cancellation or termination that would materially and adversely affect the rights of any Participant with respect to any Award theretofore granted shall not to that extent be effective without the consent of the affected Participant unless the Committee determines that such waiver, amendment, alteration, suspension, discontinuance, cancellation or termination is either required or advisable in order for the Company, the Plan or the Award to satisfy any applicable law or regulation; and provided, further, that except as otherwise permitted under Section 11 of the Plan, if (i) the Committee reduces the Exercise Price of any Option or the Strike Price of any SAR, (ii) the Committee cancels any outstanding Option or SAR and replaces it with a new Option or SAR (with a lower Exercise Price or Strike Price, as the case may be) or other Award or cash in a manner that would either (A) be reportable on the Company's proxy statement or

Form 10-K (if applicable) as Options that have been "repriced" (as such term is used in Item 402 of Regulation S-K promulgated under the Exchange Act), or (B) result in any "repricing" for financial statement reporting purposes (or otherwise cause the Award to fail to qualify for equity accounting treatment), (iii) the Committee takes any other action that is considered a "repricing" for purposes of the stockholder approval rules of the applicable securities exchange or inter-dealer quotation service on which the Common Stock is listed or quoted, or (iv) the Committee cancels any outstanding Option or SAR that has a per-share Exercise Price or Strike Price (as applicable) at or above the Fair Market Value of a share of Common Stock on the date of cancellation, and pays any consideration to the holder thereof, whether in cash, securities, or other property, or any combination thereof, then, in the case of the immediately preceding clauses (i) through (iv), any such action shall not be effective without stockholder approval.

14. General.

(a) Award Agreements; Other Agreements. Each Award under the Plan shall be evidenced by an Award Agreement, which shall be delivered to the Participant and shall specify the terms and conditions of the Award and any rules applicable thereto. In the event of any conflict between the terms of the Plan and any Award Agreement or employment, change-in-control, severance or other agreement in effect with the Participant, the term of the Plan shall control.

(b) Nontransferability.

(i) Each Award shall be exercisable only by the Participant during the Participant's lifetime, or, if permissible under applicable law, by the Participant's legal guardian or representative. No Award may be assigned, alienated, pledged, attached, sold or otherwise transferred or encumbered by the Participant other than by will or by the laws of descent and distribution, and any such purported assignment, alienation, pledge, attachment, sale, transfer or encumbrance shall be void and unenforceable against the Company or an Affiliate; provided, that the designation of a beneficiary shall not constitute an assignment, alienation, pledge, attachment, sale, transfer or encumbrance.

(ii) Notwithstanding the foregoing, the Committee may permit Awards (other than Incentive Stock Options) to be transferred by the Participant, without consideration, subject to such rules as the Committee may adopt, to (A) any person who is a "family member" of the Participant, as such term is used in the instructions to Form S-8 under the Securities Act or any successor form of registration statements promulgated by the Securities and Exchange Commission (collectively, the "**Immediate Family Members**"); (B) a trust solely for the benefit of the Participant or the Participant's Immediate Family Members; (C) a partnership or limited liability company whose only partners or stockholders are the Participant and the Participant's Immediate Family Members; or (D) any other transferee as may be approved either (1) by the Board or the Committee, or (2) as provided in the applicable Award Agreement; (each transferee described in clause (A), (B), (C) or (D) above is hereinafter referred to as a "**Permitted Transferee**"); provided, that the Participant gives the Committee advance written notice describing the terms and conditions of the proposed transfer and the Committee notifies

the Participant in writing that such a transfer would comply with the requirements of the Plan.

(iii) The terms of any Award transferred in accordance with the immediately preceding paragraph shall apply to the Permitted Transferee, and any reference in the Plan, or in any applicable Award Agreement, to the Participant shall be deemed to refer to the Permitted Transferee, except that (A) Permitted Transferees shall not be entitled to transfer any Award, other than by will or the laws of descent and distribution; (B) Permitted Transferees shall not be entitled to exercise any transferred Option unless there shall be in effect a registration statement on an appropriate form covering the shares of Common Stock to be acquired pursuant to the exercise of such Option if the Committee determines, consistent with any applicable Award Agreement, that such a registration statement is necessary or appropriate; (C) the Committee or the Company shall not be required to provide any notice to a Permitted Transferee, whether or not such notice is or would otherwise have been required to be given to the Participant under the Plan or otherwise; (D) the consequences of the termination of the Participant's employment by, or services to, the Company or an Affiliate under the terms of the Plan and the applicable Award Agreement shall continue to be applied with respect to the transferred Award, including, without limitation, that an Option shall be exercisable by the Permitted Transferee only to the extent, and for the periods, specified in the Plan and the applicable Award Agreement; and (E) any non-competition, non-solicitation, non-disparagement, non-disclosure, or other restrictive covenants contained in any Award Agreement or other agreement between the Participant and the Company or any Affiliate shall continue to apply to the Participant and the consequences of the violation of such covenants shall continue to be applied with respect to the transferred Award, including without limitation the clawback and forfeiture provisions of Section 14(v) of the Plan.

(c) Dividends and Dividend Equivalents. The Committee may provide the Participant with dividends or dividend equivalents as part of an Award, payable in cash, shares of Common Stock, other securities, other Awards or other property, on a current or deferred basis, on such terms and conditions as may be determined by the Committee, including, without limitation, payment directly to the Participant, withholding of such amounts by the Company subject to vesting of the Award or reinvestment in additional shares of Common Stock, Restricted Stock or other Awards; provided, that no dividends or dividend equivalents shall be payable (i) in respect of outstanding Options or SARs or (ii) in respect of any other Award unless and until the Participant vests in such underlying Award; provided, further, that dividend equivalents may be accumulated in respect of unearned Awards and paid as soon as administratively practicable, but no more than 60 days, after such Awards are earned and become payable or distributable (and the right to any such accumulated dividends or dividend equivalents shall be forfeited upon the forfeiture of the Award to which such dividends or dividend equivalents relate).

(d) Tax Withholding.

(i) The Participant shall be required to pay to the Company or any Affiliate, and the Company or any Affiliate shall have the right (but not the obligation) and is hereby authorized to withhold, from any cash, shares of Common Stock, other

securities or other property deliverable under any Award or from any compensation or other amounts owing to the Participant, the amount (in cash, Common Stock, other securities or other property) of any required withholding taxes (up to the maximum permissible withholding amounts) in respect of an Award, its exercise, or any payment or transfer under an Award or under the Plan and to take such other action that the Committee or the Company deem necessary to satisfy all obligations for the payment of such withholding taxes.

(ii) Without limiting the generality of paragraph (i) above, the Committee may permit the Participant to satisfy, in whole or in part, the foregoing withholding liability by (A) payment in cash, (B) the delivery of shares of Common Stock (which shares are not subject to any pledge or other security interest) owned by the Participant having a Fair Market Value on such date equal to such withholding liability or (C) having the Company withhold from the number of shares of Common Stock otherwise issuable or deliverable pursuant to the exercise or settlement of the Award a number of shares with a Fair Market Value on such date equal to such withholding liability. In addition, subject to any requirements of applicable law, the Participant may also satisfy the tax withholding obligations by other methods, including selling shares of Common Stock that would otherwise be available for delivery, provided that the Board or the Committee has specifically approved such payment method in advance.

(e) No Claim to Awards; No Rights to Continued Employment, Directorship or Engagement. No employee, director of the Company, consultant providing service to the Company or an Affiliate, or other person, shall have any claim or right to be granted an Award under the Plan or, having been selected for the grant of an Award, to be selected for a grant of any other Award. There is no obligation for uniformity of treatment of Participants or holders or beneficiaries of Awards. The terms and conditions of Awards and the Committee's determinations and interpretations with respect thereto need not be the same with respect to each Participant and may be made selectively among Participants, whether or not such Participants are similarly situated. Neither the Plan nor any action taken hereunder shall be construed as giving any Participant any right to be retained in the employ or service of the Company or an Affiliate, or to continue in the employ or the service of the Company or an Affiliate, nor shall it be construed as giving any Participant who is a director any rights to continued service on the Board.

(f) International Participants. With respect to Participants who reside or work outside of the United States, the Committee may amend the terms of the Plan or appendices thereto, or outstanding Awards, with respect to such Participants, in order to conform such terms with or accommodate the requirements of local laws, procedures or practices or to obtain more favorable tax or other treatment for the Participant, the Company or its Affiliates. Without limiting the generality of this subsection, the Committee is specifically authorized to adopt rules, procedures and sub-plans with provisions that limit or modify rights on death, disability, retirement or other terminations of employment, available methods of exercise or settlement of an Award, payment of income, social insurance contributions or payroll taxes, withholding procedures and handling of any stock certificates or other indicia of ownership that vary with local requirements. The Committee may also adopt rules, procedures or sub-plans applicable to particular Affiliates or locations.

(g) Beneficiary Designation. The Participant's beneficiary shall be the Participant's spouse (or domestic partner if such status is recognized by the Company and in such jurisdiction), or if the Participant is otherwise unmarried at the time of death, the Participant's estate, except to the extent that a different beneficiary is designated in accordance with procedures that may be established by the Committee from time to time for such purpose. Notwithstanding the foregoing, in the absence of a beneficiary validly designated under such Committee-established procedures and/or applicable law who is living (or in existence) at the time of death of a Participant residing or working outside the United States, any required distribution under the Plan shall be made to the executor or administrator of the estate of the Participant, or to such other individual as may be prescribed by applicable law.

(h) Termination of Employment or Service. The Committee, in its sole discretion, shall determine the effect of all matters and questions related to the termination of employment of or service of a Participant. Except as otherwise provided in an Award Agreement, or any employment, consulting, change-in-control, severance or other agreement between the Participant and the Company or an Affiliate, unless determined otherwise by the Committee: (i) neither a temporary absence from employment or service due to illness, vacation or leave of absence (including, without limitation, a call to active duty for military service through a Reserve or National Guard unit) nor a transfer from employment or service with the Company to employment or service with an Affiliate (or vice versa) shall be considered a termination of employment or service with the Company or an Affiliate; and (ii) if the Participant's employment with the Company or its Affiliates terminates, but such Participant continues to provide services with the Company or its Affiliates in a non-employee capacity (including as a non-employee director) (or vice versa), such change in status shall not be considered a termination of employment or service with the Company or an Affiliate for purposes of the Plan.

(i) No Rights as a Stockholder. Except as otherwise specifically provided in the Plan or any Award Agreement, no person shall be entitled to the privileges of ownership in respect of shares of Common Stock that are subject to Awards hereunder until such shares have been issued or delivered to that person.

(j) Government and Other Regulations.

(i) Nothing in the Plan shall be deemed to authorize the Committee or Board or any members thereof to take any action contrary to applicable law or regulation, or Nasdaq rules or the rules of any other securities exchange or inter-dealer quotation service on which the Common Stock is listed or quoted.

(ii) The obligation of the Company to settle Awards in Common Stock or other consideration shall be subject to all applicable laws, rules, and regulations, and to such approvals by governmental agencies as may be required. Notwithstanding any terms or conditions of any Award to the contrary, the Company shall be under no obligation to offer to sell or to sell, and shall be prohibited from offering to sell or selling, any shares of Common Stock pursuant to an Award unless such shares have been properly registered for sale pursuant to the Securities Act with the Securities and Exchange Commission or unless the Company has received an opinion of counsel, satisfactory to the Company, that

such shares may be offered or sold without such registration pursuant to and in compliance with the terms of an available exemption. The Company shall be under no obligation to register for sale under the Securities Act any of the shares of Common Stock to be offered or sold under the Plan. The Committee shall have the authority to provide that all shares of Common Stock or other securities of the Company or any Affiliate delivered under the Plan shall be subject to such stop-transfer orders and other restrictions as the Committee may deem advisable under the Plan, the applicable Award Agreement, U.S. federal securities laws, or the rules, regulations and other requirements of the U.S. Securities and Exchange Commission, any securities exchange or inter-dealer quotation service upon which such shares or other securities of the Company are then listed or quoted and any other applicable federal, state, local or non-U.S. laws, rules, regulations and other requirements, and, without limiting the generality of Section 9 of the Plan, the Committee may cause a legend or legends to be put on any such certificates of Common Stock or other securities of the Company or any Affiliate delivered under the Plan to make appropriate reference to such restrictions or may cause such Common Stock or other securities of the Company or any Affiliate delivered under the Plan in book-entry form to be held subject to the Company's instructions or subject to appropriate stop-transfer orders. Notwithstanding any provision in the Plan to the contrary, the Committee reserves the right to add any additional terms or provisions to any Award granted under the Plan that it in its sole discretion deems necessary or advisable in order that such Award complies with the legal requirements of any governmental entity to whose jurisdiction the Award is subject.

(iii) The Committee may cancel an Award or any portion thereof if it determines that legal or contractual restrictions and/or blockage and/or other market considerations would make the Company's acquisition of shares of Common Stock from the public markets, the Company's issuance of Common Stock to the Participant, the Participant's acquisition of Common Stock from the Company and/or the Participant's sale of Common Stock to the public markets illegal, impracticable or inadvisable. If the Committee determines to cancel all or any portion of an Award in accordance with the foregoing, unless prevented by applicable laws, the Company shall pay to the Participant an amount equal to the excess of (A) the aggregate Fair Market Value of the shares of Common Stock subject to such Award or portion thereof canceled (determined as of the applicable exercise date, or the date that the shares would have been vested or delivered, as applicable), over (B) the aggregate Exercise Price or Strike Price (in the case of an Option or SAR, respectively) or any amount payable as a condition of delivery of shares of Common Stock (in the case of any other Award). Such amount shall be delivered to the Participant as soon as practicable following the cancellation of such Award or portion thereof.

(k) Section 83(b) Elections. If a Participant, in connection with the acquisition of shares of Common Stock under the Plan, makes an election under Section 83(b) of the Code, the Participant shall notify the Company of such election within ten days after filing notice of the election with the Internal Revenue Service, in addition to any filing and notification required pursuant to Section 83(b) of the Code.

(l) Payments to Persons Other Than Participants. If the Committee shall find that any person to whom any amount is payable under the Plan is unable to care for such person's affairs because of illness or accident, or is a minor, or has died, then any payment due to such person or such person's estate (unless a prior claim therefor has been made by a duly appointed legal representative or a beneficiary designation form has been filed with the Company) may, if the Committee so directs the Company, be paid to such person's spouse, child, or relative, or an institution maintaining or having custody of such person, or any other person deemed by the Committee to be a proper recipient on behalf of such person otherwise entitled to payment. Any such payment shall be a complete discharge of the liability of the Committee and the Company therefor.

(m) Nonexclusivity of the Plan. Neither the adoption of the Plan by the Board nor the submission of the Plan to the stockholders of the Company for approval shall be construed as creating any limitations on the power of the Board to adopt such other incentive arrangements as it may deem desirable, including, without limitation, the granting of stock options or awards otherwise than under the Plan, and such arrangements may be either applicable generally or only in specific cases.

(n) No Trust or Fund Created. This Plan and Awards hereunder are intended to be unfunded for tax purposes and for purposes of the Employee Retirement Income Security Act of 1974, as amended, and shall be construed and interpreted in accordance with such intent. Neither the Plan nor any Award shall create or be construed to create a trust or separate fund of any kind or a fiduciary relationship between the Company or any Affiliate, on the one hand, and the Participant or other person or entity, on the other hand. No provision of the Plan or any Award shall require the Company, for the purpose of satisfying any obligations under the Plan, to purchase assets or place any assets in a trust or other entity to which contributions are made or to otherwise segregate any assets, nor shall the Company maintain separate bank accounts, books, records or other evidence of the existence of a segregated or separately maintained or administered fund for such purposes. Participants shall have no rights under the Plan other than as unsecured general creditors of the Company.

(o) Reliance on Reports. Each member of the Committee and each member of the Board (and each such member's respective designees) shall be fully justified in acting or failing to act, as the case may be, and shall not be liable for having so acted or failed to act in good faith, in reliance upon any report made by the independent registered public accounting firm of the Company or any of its Affiliates or any other information furnished in connection with the Plan by any agent or advisor of the Company or the Committee or the Board.

(p) Relationship to Other Benefits. No payment under the Plan shall be taken into account in determining any benefits under any pension, retirement, profit sharing, group insurance or other benefit plan of the Company except as otherwise specifically provided in such other plan.

(q) Purchase for Investment. Whether or not the Options and shares covered by the Plan have been registered under the Securities Act, each person exercising an Option under the Plan or acquiring shares under the Plan may be required by the Company to give a representation in writing that such person is acquiring such shares for investment and not with a

view to, or for sale in connection with, the distribution of any part thereof. The Company will endorse any necessary legend referring to the foregoing restriction upon the certificate or certificates representing any shares issued or transferred to the Participant upon the exercise of any Option granted under the Plan.

(r) Governing Law. The Plan shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to principles of conflicts of laws thereof, or principles of conflicts of laws of any other jurisdiction that could cause the application of the laws of any jurisdiction other than the State of Delaware.

(s) Severability. If any provision of the Plan or any Award or Award Agreement is or becomes or is deemed to be invalid, illegal, or unenforceable in any jurisdiction or as to any person or entity or Award, or would disqualify the Plan or any Award under any law deemed applicable by the Committee, such provision shall be construed or deemed amended to conform to the applicable laws, or if it cannot be construed or deemed amended without, in the determination of the Committee, materially altering the intent of the Plan or the Award, such provision shall be construed or deemed stricken as to such jurisdiction, person or entity or Award, and the remainder of the Plan and any such Award shall remain in full force and effect.

(t) Obligations Binding on Successors. The obligations of the Company under the Plan shall be binding upon any successor corporation or organization resulting from the merger, consolidation or other reorganization of the Company, or upon any successor corporation or organization succeeding to all or substantially all of the assets and business of the Company.

(u) Section 409A of the Code.

(i) It is intended that the Plan be exempt from or comply with Section 409A of the Code, and all provisions of the Plan shall be construed and interpreted in a manner consistent with the requirements for avoiding taxes or penalties under Section 409A of the Code. Each Participant is solely responsible and liable for the satisfaction of all taxes and penalties that may be imposed on or in respect of such Participant in connection with the Plan or any other plan maintained by the Company, including any taxes and penalties under Section 409A of the Code, and neither the Company nor any Affiliate shall have any obligation to indemnify or otherwise hold such Participant or any beneficiary harmless from any or all of such taxes or penalties. With respect to any Award that is considered "deferred compensation" subject to Section 409A of the Code, references in the Plan to "termination of employment" (and substantially similar phrases) shall mean "separation from service" within the meaning of Section 409A of the Code. For purposes of Section 409A of the Code, each of the payments that may be made in respect of any Award granted under the Plan is designated as a separate payment.

(ii) Notwithstanding anything in the Plan to the contrary, if the Participant is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, no payments or deliveries in respect of any Awards that are payable on account of the Participant's "separation from service" and that are "deferred compensation" subject to Section 409A of the Code shall be made to such Participant prior to the date

that is six months after the date of such Participant's "separation from service" within the meaning of Section 409A of the Code or, if earlier, the Participant's date of death. All such delayed payments or deliveries will be paid or delivered (without interest) in a single lump sum on the earliest date permitted under Section 409A of the Code that is also a business day.

(iii) In the event that the timing of payments in respect of any Award that would otherwise be considered "deferred compensation" subject to Section 409A of the Code would be accelerated upon the occurrence of (A) a Change in Control, no such acceleration shall be permitted unless the event giving rise to the Change in Control satisfies the definition of a change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portion of the assets of a corporation pursuant to Section 409A of the Code and any Treasury Regulations promulgated thereunder or (B) a Disability, no such acceleration shall be permitted unless the Disability also satisfies the definition of "disability" pursuant to Section 409A of the Code and any Treasury Regulations promulgated thereunder.

(v) Clawback/Forfeiture. Notwithstanding anything to the contrary contained herein, to the extent required by applicable law (including, without limitation, Section 304 of the Sarbanes-Oxley Act and Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder) and/or the rules and regulations of NASDAQ or any other securities exchange or inter-dealer quotation service on which the Common Stock is listed or quoted, Awards shall be subject (including on a retroactive basis) to clawback, forfeiture or similar requirements (and such requirements shall be deemed incorporated by reference into all outstanding Award Agreements).

(w) No Representations or Covenants with Respect to Tax Qualification. Although the Company may endeavor to (i) qualify an Award for favorable U.S. or non-U.S. tax treatment or (ii) avoid adverse tax treatment, the Company makes no representation to that effect and expressly disavows any covenant to maintain favorable or avoid unfavorable tax treatment. The Company shall be unconstrained in its corporate activities without regard to the potential negative tax impact on holders of Awards under the Plan.

(x) No Interference. The existence of the Plan, any Award Agreement, and the Awards granted hereunder shall not affect or restrict in any way the right or power of the Company, the Board, the Committee, or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization, or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock or of options, warrants, or rights to purchase stock or of bonds, debentures, or preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or that are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company or any Affiliate, or any sale or transfer of all or any part of their assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

(y) Expenses; Titles and Headings. The expenses of administering the Plan shall be borne by the Company and its Affiliates. The titles and headings of the sections in the

Plan are for convenience of reference only, and in the event of any conflict, the text of the Plan, rather than such titles or headings shall control.

* * *

As approved by the Board of Directors of the Company on March 9, 2018 and as adopted by the stockholders of the Company on June 6, 2018, and as amended by the Board of Directors of the Company on March 24, 2020 and adopted by the stockholders of the Company on June 8, 2020, and as amended by the Board of Directors of the Company on March 7, 2022 and adopted by the stockholders of the Company on June 10, 2022, and as amended by the Committee on June 10, 2022, and as amended by the Board of Directors on April 18, 2023 and adopted by the stockholders of the Company on June 6, 2023, and as amended by the Committee on February 26, 2024, and as amended by the Committee on April 18, 2024 and adopted by the stockholders of the Company on June 11, 2024, and as further amended by the Board of Directors on April 21, 2025 and adopted by the stockholders of the Company on June 10, 2025.

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: August 7, 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, Matthew W. Rosinack, Principal Financial and Accounting 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: August 7, 2025

By: /s/ Matthew W. Rosinack
Matthew W. Rosinack
Principal Financial and Accounting Officer

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Iovance Biotherapeutics, Inc. (the "Company") for the quarter ended June 30, 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: August 7, 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 June 30, 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: August 7, 2025

By: /s/ Matthew W. Rosinack
Matthew W. Rosinack
Principal Financial and 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.