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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

OR

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

For the transition period from _____ to

Commission File Number: 001-38359

Adicet Bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**81-3305277**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
131 Dartmouth Street, 3rd Floor Boston, MA	**02116**
(Address of principal executive offices)	**(Zip Code)**

(650) 503-9095
(Registrant's telephone number, including area code)

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 $0.0001 per share	**ACET**	**The Nasdaq Capital Market**

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

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

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

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

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

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

As of November 3, 2026, the registrant had 9,361,596 shares of common stock, $0.0001 par value per share, outstanding.

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Summary of the Material Risks Associated with Our Business

- We have a limited operating history and face significant challenges and expenses as we build our capabilities.
- Our business is highly dependent on the success of prula-cel (formerly ADI-001). If we are unable to obtain regulatory approval for prula-cel in one or more indications and effectively commercialize this product candidate for the treatment of patients in indications for which we receive approval (if any), our business would be significantly harmed.
- Our gamma delta T cell candidates represent a novel approach to the treatment of autoimmune diseases and cancer indications that creates significant challenges for us.
- Our product candidates are based on novel technologies, which makes it difficult to predict the likely success of such product candidates and the time and cost of product candidate development and obtaining regulatory approval.
- Our clinical trials may fail to demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.
- We may not be able to file Investigational New Drug (IND) applications, or comparable regulatory submissions, to commence additional clinical trials on the timelines we expect, and even if we are able to, the U.S. Food and Drug Administration (FDA) or analogous regulatory authorities may not permit us to proceed.
- We may encounter substantial delays in our clinical trials, or may not be able to conduct our trials on the timelines we expect.
- The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.
- We may not realize the anticipated benefits of our workforce reduction and strategic pipeline prioritization.
- Although we have commenced manufacturing operations at our manufacturing facility, we currently depend on the ability of our third-party suppliers and manufacturers with whom we contract to perform adequately, particularly with respect to the timely production and delivery of our product candidates, including prula-cel. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- We will need substantial additional financing to develop our product candidates and implement our operating plans. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates.
- The pharmaceutical industry in China is highly regulated and such regulations, including the Foreign Investment Law and the "negative list," are subject to change which may affect development, approval and commercialization of our product candidates.
- The uncertainties in the People's Republic of China's legal system regarding the Foreign Investment Law may subject our contractual arrangements to different interpretations or enforcement challenges, subject us to severe penalties or force us to relinquish our interests in our operations.
- Business disruptions, including armed conflicts, could substantially delay our clinical trials or seriously harm our future revenue and financial condition and increase our costs and expenses.
- A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business, including the potential impact of global conflicts on our supply or clinical trials.
- Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.
- We have in the past failed and may in the future fail to achieve and maintain effective internal control over financial reporting, which could harm our business and negatively impact the value of our common stock.

- If our collaboration with Regeneron Pharmaceuticals, Inc. (Regeneron) is terminated, or if Regeneron materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition would be materially harmed.
- Our existing and future collaborations will be important to our business. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.
- The FDA 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.
- If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- The trading price of our common stock is highly volatile, which could result in substantial losses for purchasers of our common stock. Securities class action or other litigation involving our company or members of our management team could also substantially harm our business, financial condition and results of operations.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- the timing of and our ability to execute our clinical trials for prula-cel in autoimmune indications, including the ability to successfully complete our Phase 1 clinical trial in lupus nephritis (LN) and initiate Phase 1 clinical trials in lupus erythematosus (SLE), systemic sclerosis (SSc), anti-neutrophil cytoplasmic autoantibody associated vasculitis (AAV), idiopathic inflammatory myopathy (IIM), stiff person syndrome (SPS) and rheumatoid arthritis (RA);
- the timing, costs and effects of our workforce reduction and strategic pipeline prioritization;
- our expectations regarding the preclinical development of ADI-212, and our ability to develop other product candidates in our research pipeline;
- our expectations regarding prula-cel, including site activation and enrollment for and the availability, timing and announcement of data from our Phase 1 clinical trials for prula-cel and timing and plans for a potential Phase 2 pivotal trial;
- our expectations regarding discussions with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) of a potential path to support Biologics License Applications (BLA) and Marketing Authorization Applications (MAA) for our product candidates;
- the anticipated timing of our submission of Investigational New Drug (IND) applications or equivalent regulatory filings and initiation of future clinical trials, including the timing of the anticipated results;
- our expectations regarding the impact of unstable market and economic conditions, including impacts of inflation, tariffs and adverse developments affecting the financial services industry, on our business, results of operations or financial conditions;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of acceptance and clinical utility of any products for which we receive regulatory approval;
- our expectations regarding the manufacturing of our product candidates and any products for which we receive regulatory approval by us or by our third-party suppliers;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional product candidates with significant commercial potential;
- our plans to enter into collaborations for the development and commercialization of product candidates;
- the potential benefits of any current and future collaboration;
- our research and development activities outside of the United States, including in China, and related contractual relationships;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the success of competing therapies that are or may become available;
- developments relating to our competitors and our industry;
- our ability to retain the continued service of our key professionals and to identify, hire, and retain additional qualified professionals;

- our financial performance;
- our expectations related to the use of cash, cash equivalents and short-term investments in treasury securities;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to maintain effective internal control over financial reporting;
- the impact of government laws and regulations; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we reference herein and have filed or incorporated by reference as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This Quarterly Report on Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this Quarterly Report on Form 10-Q, and we believe these industry publications and third-party research, surveys and studies are reliable.

PART I—FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements (Unaudited).

ADICET BIO, INC.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 27,111	$ 38,918
Short-term investments in treasury securities	73,834	119,612
Prepaid expenses and other current assets	2,497	2,396
Total current assets	103,442	160,926
Restricted cash	2,574	2,872
Property and equipment, net	13,066	16,532
Operating lease right-of-use asset	8,930	10,927
Finance lease right-of-use asset	854	1,022
Other non-current assets	80	76
Total assets	$ 128,946	$ 192,355
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,700	$ 4,739
Accrued and other current liabilities	11,449	13,606
Operating lease liability	2,673	2,837
Finance lease liability	174	349
Total current liabilities	16,996	21,531
Operating lease liability, net of current portion	8,621	10,910
Finance lease liability, net of current portion	632	642
Other non-current liabilities	—	62
Total liabilities	26,249	33,145
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized as of September 30, 2026 and December 31, 2025, respectively; none issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized as of September 30, 2026 and December 31, 2025, respectively; 9,361,596 and 9,586,770 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	1	10
Additional paid-in capital	778,048	773,795
Accumulated deficit	(675,177)	(614,697)
Accumulated other comprehensive (loss) income	(175)	102
Total stockholders' equity	102,697	159,210
Total liabilities and stockholders' equity	$ 128,946	$ 192,355

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

ADICET BIO, INC.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 15,626	$ 22,853	$ 51,562	$ 74,091
General and administrative	4,170	5,099	12,105	16,137
Total operating expenses	19,796	27,952	63,667	90,228
Loss from operations	(19,796)	(27,952)	(63,667)	(90,228)
Interest income	972	1,172	3,482	4,253
Interest expense	(23)	(12)	(68)	(12)
Other expense, net	(30)	(64)	(83)	(300)
Loss before income tax provision	(18,877)	(26,856)	(60,336)	(86,287)
Income tax provision	(1)	—	(144)	—
Net loss	$ (18,878)	$ (26,856)	$ (60,480)	$ (86,287)
Net loss per share, basic and diluted	$ (1.76)	$ (4.72)	$ (5.62)	$ (15.10)
Weighted-average common shares used in computing net loss per share, basic and diluted	10,745,696	5,692,874	10,753,547	5,713,216
Other comprehensive income				
Unrealized gain (loss) on treasury securities, net of tax	(70)	97	(277)	40
Total other comprehensive income (loss)	(70)	97	(277)	40
Comprehensive loss	$ (18,948)	$ (26,759)	$ (60,757)	$ (86,247)

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

ADICET BIO, INC.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2025	9,586,770	$ 10	$ 773,795	$ (614,697)	$ 102	$ 159,210
Immaterial correction from par to additional paid-in capital	—	(9)	9	—	—	—
Issuance of common stock upon vesting of restricted stock	19,555	—	—	—	—	—
Shares withheld for taxes	(8,632)	—	(65)	—	—	(65)
Stock-based compensation expense	—	—	1,303	—	—	1,303
Net loss	—	—	—	(20,244)	—	(20,244)
Other comprehensive income (loss)	—	—	—	—	(139)	(139)
Balance at March 31, 2026	9,597,693	$ 1	$ 775,042	$ (634,941)	$ (37)	$ 140,065
Issuance of common stock upon exercise of stock options	105	—	1	—	—	1
Issuance of common stock upon vesting of restricted stock	2,620	—	—	—	—	—
Shares withheld for taxes	(272)	—	(3)	—	—	(3)
Exchange of common stock for pre-funded warrant, net of issuance costs of $22	(250,000)	—	(22)	—	—	(22)
Purchase of common stock under Employee Stock Purchase Plan	11,225	—	82	—	—	82
Stock-based compensation expense	—	—	1,441	—	—	1,441
Net loss	—	—	—	(21,358)	—	(21,358)
Other comprehensive income (loss)	—	—	—	—	(68)	(68)
Balance at June 30, 2026	9,361,371	$ 1	$ 776,541	$ (656,299)	$ (105)	$ 120,138
Issuance of common stock upon exercise of stock options	152	—	1	—	—	1
Issuance of common stock upon vesting of restricted stock	107	—	—	—	—	—
Shares withheld for taxes	(34)	—	—	—	—	—
Stock-based compensation expense	—	—	1,506	—	—	1,506
Net loss	—	—	—	(18,878)	—	(18,878)
Other comprehensive income (loss)	—	—	—	—	(70)	(70)
Balance at September 30, 2026	9,361,596	$ 1	$ 778,048	$ (675,177)	$ (175)	$ 102,697

ADICET BIO, INC.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2024	5,160,545	$ 5	$ 684,482	$ (497,894)	$ 16	$ 186,609
Issuance of common stock upon vesting of restricted stock	15,943	—	—	—	—	—
Shares withheld for taxes	(7,161)	—	(104)	—	—	(104)
Stock-based compensation expense	—	—	3,180	—	—	3,180
Net loss	—	—	—	(28,214)	—	(28,214)
Other comprehensive income (loss)	—	—	—	—	(25)	(25)
Balance at March 31, 2025	5,169,327	$ 5	$ 687,558	$ (526,108)	$ (9)	$ 161,446
Issuance of common stock upon vesting of restricted stock	1,840	—	—	—	—	—
Purchase of common stock under Employee Stock Purchase Plan	32,063	—	267	—	—	267
Stock-based compensation expense	—	—	2,908	—	—	2,908
Net loss	—	—	—	(31,217)	—	(31,217)
Other comprehensive income (loss)	—	—	—	—	(32)	(32)
Balance at June 30, 2025	5,203,230	$ 5	$ 690,733	$ (557,325)	$ (41)	$ 133,372
Issuance of common stock upon vesting of restricted stock	129	—	—	—	—	—
Shares withheld for taxes	(52)	—	—	—	—	—
Stock-based compensation expense	—	—	2,529	—	—	2,529
Net loss	—	—	—	(26,856)	—	(26,856)
Other comprehensive income (loss)	—	—	—	—	97	97
Balance at September 30, 2025	5,203,307	$ 5	$ 693,262	$ (584,181)	$ 56	$ 109,142

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

ADICET BIO, INC.
Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities		
Net loss	$ (60,480)	$ (86,287)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	3,580	4,908
Noncash lease expense	2,161	2,355
Stock-based compensation expense	4,250	8,617
Loss on disposal of property and equipment	—	103
Net amortization of premiums and accretion of discounts on investments	(1,928)	(2,881)
Amortization of deferred transaction costs	—	15
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(102)	490
Other non-current assets	(1)	304
Accounts payable	(2,028)	722
Operating lease liability	(2,635)	(2,653)
Accrued and other current and non-current liabilities	(2,050)	(30)
Net cash used in operating activities	(59,233)	(74,337)
Cash flows from investing activities		
Purchases of short-term treasury securities	(60,571)	(61,324)
Maturities of short-term treasury securities	108,000	110,000
Purchases of property and equipment	(295)	(1,748)
Net cash provided by (used in) investing activities	47,134	46,928
Cash flows from financing activities		
Proceeds from exercise of stock options	2	—
Proceeds from Employee Stock Purchase Plan	82	267
Pre-funded warrant issuance costs	(22)	—
Taxes withheld and paid related to net share settlement of equity awards	(68)	(104)
Principal payments on finance leases	—	(150)
Net cash (used in) provided by financing activities	(6)	13
Net change in cash, cash equivalents and restricted cash	(12,105)	(27,396)
Cash, cash equivalents and restricted cash at the beginning of period	41,790	59,398
Cash, cash equivalents and restricted cash at the end of period	$ 29,685	$ 32,002
Reconciliation of cash, cash equivalents and restricted cash to consolidated balance sheets:		
Cash and cash equivalents	$ 27,111	$ 29,099
Restricted cash	2,574	2,903
Cash, cash equivalents and restricted cash in consolidated balance sheets	$ 29,685	$ 32,002
Supplemental cash flow information		
Supplemental disclosures of noncash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 28	$ 208
Right-of-use asset acquired under finance leases	$ —	$ 1,104
Remeasurement of finance lease resulting in a reduction of ROU asset	$ 4	$ —

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

ADICET BIO, INC.
Notes to Interim Consolidated Financial Statements (Unaudited)

1. Organization and Nature of the Business

Adicet Bio, Inc. (formerly resTORbio, Inc. (resTORbio), together with its subsidiaries, the Company) is a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer. The Company is advancing a pipeline of "off-the-shelf" gamma delta T cells, engineered with chimeric antigen receptors (CARs), to facilitate durable activity in patients.

Adicet Bio, Inc. (when referred to prior to the merger, Former Adicet) was incorporated in November 2014 in Delaware. On September 15, 2020, Former Adicet completed a merger (Merger) with resTORbio, pursuant to which Former Adicet merged with a wholly owned subsidiary of resTORbio in an all-stock transaction with Former Adicet surviving as a wholly owned subsidiary of resTORbio and changing its name to "Adicet Therapeutics, Inc." (Adicet Therapeutics). In connection with the Merger, the Company changed its name from "resTORbio, Inc." to "Adicet Bio, Inc." The Company's principal executive offices are located in Boston, Massachusetts. The Company also has offices in Redwood City, California.

Adicet Bio Israel Ltd. (formerly Applied Immune Technologies Ltd.) (Adicet Israel) is a wholly owned subsidiary of the Company and is located in Haifa, Israel. Adicet Israel was founded in 2006. During 2019, the Company consolidated its operations, including research and development activities, in the United States and as a result, substantially reduced its operations in Israel.

Adicet (Shanghai) Biotechnology Co., Ltd. (Adicet Shanghai) is a wholly owned subsidiary of Adicet Therapeutics and is located in Shanghai, China. Adicet Shanghai was founded in May 2024.

In May 2024, the Company initiated research and development activities in China through a series of contractual agreements entered into and among Shanghai Adicet Biotechnology Co., Ltd. (Shanghai Adicet), a variable interest entity, Adicet Shanghai, and the shareholders of Shanghai Adicet. The Company was the primary beneficiary of Shanghai Adicet which was considered a consolidated entity under accounting principles generally accepted in the United States of America (U.S. GAAP). In July 2025, Adicet Therapeutics entered into an equity transfer agreement with the then-stockholders of Shanghai Adicet to acquire 100% equity interests of Shanghai Adicet from its then-stockholders (the Acquisition). In connection with the Acquisition, tax filings and registration were completed in August 2025. As of August 2025, upon completion of the registration, Shanghai Adicet is now a wholly owned subsidiary of Adicet Therapeutics and will continue to conduct research and development activities in China. The transaction did not have a material impact on the financial statements. The Company consolidates the financial results of this entity into its consolidated financial statements in accordance with U.S. GAAP.

Liquidity and Going Concern

The Company has incurred significant net operating losses and negative cash flows from operations and has an accumulated deficit of $675.2 million as of September 30, 2026. The Company has historically financed its operations primarily through a collaboration and licensing arrangement, public and private placements of equity securities and debt, and cash received in the Merger with resTORbio. To date, none of the Company's product candidates have been approved for sale and therefore the Company has not generated any revenue from product sales. Management expects operating losses and negative cash flows to continue for the foreseeable future, until such time, if ever, that it can generate significant sales of its product candidates currently in development.

On March 12, 2021, the Company entered into a Capital On Demand™ Sales Agreement (the JonesTrading Sales Agreement) with JonesTrading Institutional Services LLC, as sales agent, to provide for the offering, issuance and sale of up to an aggregate amount of $75.0 million of shares of common stock from time to time in "at-the-market" (ATM) offerings. In August 2022, pursuant to the JonesTrading Sales Agreement and subject to the limitations thereof, the Company sold an aggregate of 163,233 shares of common stock of the Company, par value $0.0001 per share (common stock), at $275.68 per share resulting in net proceeds to the Company of $43.4 million after deducting sales agent commissions and expenses. In November 2022, the Company filed a new prospectus supplement to the 2021 Shelf Registration Statement for the offer and sale of up to $100.0 million of shares of common stock from time to time through the sales agent, which includes the $30.0 million of shares of common stock not sold under the original prospectus and up to an additional $70.0 million of shares of common stock (the JonesTrading ATM Program). In January 2024, the Company raised aggregate net proceeds of

approximately $19.3 million through the JonesTrading ATM Program. In March 2024, the Company terminated the JonesTrading ATM Program.

On January 22, 2024, the Company entered into an Underwriting Agreement (the Underwriting Agreement) with Jefferies LLC (Jefferies) and Guggenheim Securities, LLC (Guggenheim), as representatives of the underwriters (the 2024 Underwriters), related to an underwritten public offering (the Offering) of 1,690,917 shares (the Shares) of common stock, and, in lieu of common stock to an investor, pre-funded warrants (the Pre-Funded Warrants) to purchase 527,833 shares of common stock (the Warrant Shares). The Shares were sold at a public offering price of $38.40 per share and the Pre-Funded Warrants were sold at a public offering price of $38.3984 per underlying share, which represents the per share public offering price of each share of common stock minus the $0.0016 per share exercise price for each pre-funded warrant. The purchase price paid by the 2024 Underwriters to the Company was $36.096 per Share and $36.0944 per Pre-Funded Warrant, representing a discount to the 2024 Underwriters of 6.0%. In addition, the Company granted the 2024 Underwriters an option exercisable for 30 days from the date of the Underwriting Agreement to purchase, at the public offering price less underwriting discounts and commissions, up to an additional 332,813 shares of common stock. On January 23, 2024, the 2024 Underwriters exercised this option in full. The Company received net proceeds from the Offering, after deducting the underwriting discount and commissions and other offering expenses, of approximately $91.7 million. The Company may receive nominal proceeds, if any, from the exercise of the Pre-Funded Warrants.

In March 2024, the Company entered into an Open Market Sales Agreement℠ (the Jefferies Sales Agreement) with Jefferies to sell shares of its common stock from time to time, through an ATM equity offering program under which Jefferies will act as sales agent or principal. As of September 30, 2026, no shares of common stock have been sold under the Jefferies Sales Agreement.

On October 7, 2025, the Company entered into an Underwriting Agreement (the 2025 Underwriting Agreement) with Jefferies and Guggenheim, as representatives of the underwriters (the 2025 Underwriters), related to an underwritten registered direct offering (the 2025 Offering) of 4,375,062 shares (the 2025 Shares) of common stock, and, in lieu of common stock to an investor, pre-funded warrants (the 2025 Pre-Funded Warrants) to purchase 625,000 shares of common stock (the 2025 Warrant Shares). The 2025 Shares were sold at a price of $16.00 per share and the 2025 Pre-Funded Warrants were sold at a price of $15.9984 per underlying share, which represents the per share offering price of each share of common stock minus the $0.0016 per share exercise price for each pre-funded warrant. The purchase price paid by the 2025 Underwriters to the Company was $15.04 per 2025 Share and $15.03856 per 2025 Pre-Funded Warrant, representing a discount to the 2025 Underwriters of 6.0%. The Company received net proceeds from the 2025 Offering, after deducting the underwriting discount and commissions and other offering expenses, of approximately $74.8 million. The Company may receive nominal proceeds, if any, from the exercise of the 2025 Pre-Funded Warrants.

All of the Company's revenue to date has been generated from a collaboration and license agreement (the Regeneron Agreement) with Regeneron Pharmaceuticals, Inc. (Regeneron). The Company does not expect to generate any significant product revenue until it obtains regulatory approval of and commercializes any of the Company's product candidates or enters into additional collaborative agreements with third parties, and it does not know when, or if, either will occur. The Company expects to continue to incur significant losses for the foreseeable future, and it expects the losses to increase as the Company continues the development of, and seeks regulatory approvals for, its product candidates and begins to commercialize any approved products. The Company is subject to all of the risks typically related to the development of new product candidates, including, but not limited to, raising additional capital, development by its competitors of new technological innovations, risk of failure in preclinical and clinical studies, safety and efficacy of its product candidates in clinical trials, the risk of relying on external parties such as contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs), the regulatory approval process, market acceptance of the Company's products once approved, lack of marketing and sales history, dependence on key personnel and protection of proprietary technology and it may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect its business.

Until such time as the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operations through the sale of equity, debt financings, collaborative or other arrangements with corporate or other sources of financing. Adequate funding may not be available to the Company on acceptable terms or at all. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and the Company's ability to pursue its business strategies. Although the Company continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all. If unsuccessful in raising additional capital, the Company will be required to delay, reduce the scope of, or eliminate additional research and development programs, or take other cost cutting measures, or obtain funds by sale or

license of other rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves. The Company expects that its current cash and cash equivalents and short-term investments may not be sufficient to fund operations for at least twelve months from the date of issuance of these unaudited consolidated financial statements. Accordingly, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The unaudited interim consolidated financial statements and related disclosures have been prepared in conformity with U.S. GAAP. The Company's consolidated financial statements include the accounts of the Company and the accounts of the Company's wholly-owned subsidiaries, Adicet Shanghai and Shanghai Adicet, located in Shanghai, PRC and Adicet Israel, located in Haifa, Israel. All intercompany balances and transactions have been eliminated.

Reverse Stock Split

On December 30, 2025, the Company effected a 1-for-16 reverse stock split for all of its issued and outstanding shares of common stock. All share and per share amounts presented in these consolidated financial statements and accompanying notes have been retroactively adjusted where applicable, to reflect the reverse stock split. There was no change to the total number of shares authorized or par value per share as a result of this reverse stock split.

Significant Accounting Policies

The Company's significant accounting policies are described in *Note 2, "Summary of Significant Accounting Policies,"* to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025. There have been no material changes to the significant accounting policies during the nine months ended September 30, 2026.

Unaudited Interim Financial Information

The accompanying unaudited consolidated financial statements as of September 30, 2026, and for the three and nine months ended September 30, 2026, have been prepared by the Company, pursuant to the rules and regulations of the SEC, for interim financial statements. Certain information and disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2025. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's consolidated financial position as of September 30, 2026 and consolidated results of operations for the three and nine months ended September 30, 2026 and 2025 and consolidated cash flows and stockholders' equity for the nine months ended September 30, 2026 and 2025 have been made. The results of operations for the three and nine months ended September 30, 2026 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2026.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash, cash equivalents and short-term investments in treasury securities. The Company's cash and cash equivalents, as well as its short-term investments in treasury securities, are held at two financial institutions in the U.S., one financial institution in China and one financial institution in Israel and such amounts may, at times, exceed insured limits. The Company invests its cash equivalents in treasury securities and money market funds. The Company limits its credit risk associated with cash equivalents and short-term investments in treasury securities by placing them with banks and institutions it believes are highly creditworthy and in highly rated investments. The Company has not experienced any losses on its deposits of cash and cash equivalents or its short-term investments in treasury securities to date.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies, clinical trials, and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting.

The Company's product candidates are still in development and, to date, none of the Company's product candidates have been approved for sale and, therefore, the Company has not generated any revenue from product sales.

There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from other pharmaceutical and biotechnology companies.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies and adopted by the Company as of the specified effective date, unless otherwise discussed below.

Recently Adopted Accounting Pronouncements

In September 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which enhances the transparency and usefulness of income tax disclosures. This amendment requires public issuers to disclose specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5 percent of the amount computed by multiplying pretax income, or loss, by the applicable statutory income tax rate. Additionally, this amendment requires issuers to disclose the amount of income taxes paid (net of refunds received) disaggregated by federal (national), state, and foreign taxes as well as the amount of income taxes paid (net of refunds received) disaggregated by individual jurisdictions in which income taxes paid (net of refunds received) is equal to or greater than 5 percent of total income taxes paid (net of refunds received). For SEC filers, this ASU is effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company adopted ASU 2023-09 in the fourth quarter of 2025 on a prospective basis.

Accounting Pronouncements Not Yet Adopted

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 ("ASU 2024-03"),* which requires the disaggregation of certain expense captions into specified categories in disclosures within the notes to the consolidated financial statements to provide enhanced transparency into the expense captions presented on the face of the statements of income and comprehensive income. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, 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 that the adoption of ASU 2024-03 will have on its related disclosures.

3. Fair Value Measurements

The Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy which establishes three levels of inputs that may be used to measure fair value, as follows:

Level 1 — Observable inputs, such as quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs which reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

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

	September 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Treasury securities (1) (3)	$ 73,834	$ —	$ —	$ 73,834
Money market funds (2) (3)	23,550	—	—	23,550
Total fair value of assets	$ 97,384	$ —	$ —	$ 97,384

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Treasury securities (1) (3)	$ 119,612	$ —	$ —	$ 119,612
Money market funds (2) (3)	31,641	—	—	31,641
Total fair value of assets	$ 151,253	$ —	$ —	$ 151,253

(1) Included in short-term investments in treasury securities in the consolidated balance sheets. These securities have maturity dates of greater than three months, but less than twelve months from the date of purchase.
(2) Included in cash and cash equivalents in the consolidated balance sheets.
(3) Treasury securities and money market funds are included within Level 1 of the fair value hierarchy because they are actively traded and valued using quoted market prices.

4. Marketable Securities

The following tables show the Company's available-for-sale securities adjusted cost, net unrealized gains and losses and fair value by significant investment category (in thousands):

	September 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Marketable Securities:				
Treasury securities	$ 74,009	$ —	$ (175)	$ 73,834
Total	$ 74,009	$ —	$ (175)	$ 73,834

	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Marketable Securities:				
Treasury securities	$ 119,510	$ 102	$ —	$ 119,612
Total	$ 119,510	$ 102	$ —	$ 119,612

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Prepaid software subscription and licensing fees	$ 613	$ 389
Prepaid maintenance	535	338
Prepayments to CROs and CDMOs	361	185
Interest receivable	297	342
Prepaid insurance	128	829
Prepaid employee benefits	73	6
Other prepaid expenses and current assets	490	307
Total prepaid expenses and other current assets	$ 2,497	$ 2,396

6. Property and Equipment, net

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

	Useful life (in years)	September 30, 2026	December 31, 2025
Leasehold improvements	Lesser of useful life or lease term	$ 28,598	$ 28,422
Laboratory equipment	3	13,783	13,725
Furniture and fixtures	3	802	802
Construction in progress	—	78	198
Computer equipment	3	319	319
Software	3	453	453
		44,033	43,919
Less: Accumulated depreciation and amortization		(30,967)	(27,387)
Property and equipment, net		$ 13,066	$ 16,532

Depreciation and amortization expense was $1.0 million and $1.6 million for the three months ended September 30, 2026 and 2025, respectively. Depreciation and amortization expense was $3.6 million and $4.9 million for the nine months ended September 30, 2026 and 2025, respectively.

7. Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued compensation	$ 4,897	$ 5,632
Accrued CRO costs	4,467	5,707
Accrued professional services	1,029	1,200
Accrued CDMO costs	501	479
Accrued other research and development expenses	415	367
Accrued other liabilities	140	221
Total accrued and other liabilities	$ 11,449	$ 13,606

8. Third Party Agreements

Regeneron

On July 29, 2016, the Company entered into a license and collaboration agreement with Regeneron, which was amended in April 2019, with such amendment becoming effective in connection with Regeneron's investment in the

Company's Series B redeemable convertible preferred stock private placement transaction in July 2019 (as amended, the Regeneron Agreement).

Financial Terms. The Company received a non-refundable upfront payment of $25.0 million from Regeneron upon execution of the Regeneron Agreement and an aggregate of $20.0 million of additional payments for research funding from Regeneron as of September 30, 2026. In addition, Regeneron may have to pay the Company additional amounts in the future consisting of up to an aggregate of $80.0 million of option exercise fees, as specified in the Regeneron Agreement. Per the terms of the agreement, Regeneron must pay the Company high single digit royalties as a percentage of net sales for immune cell products (ICPs) to targets for which it has exclusive rights, and low single digit royalties as a percentage of net sales on any non-ICP product comprising a targeting moiety generated by the Company through the use of Regeneron's proprietary mice. The Company must pay Regeneron mid-single to low double digit, but less than teens, of royalties as a percentage of net sales of ICPs to targets for which the Company has exercised exclusive rights, and low to mid-single digit of royalties as a percentage of net sales of targeting moieties generated from the Company's license to use Regeneron's proprietary mice. Royalties are payable until the longer of the expiration or invalidity of the licensed patent rights or twelve (12) years from first commercial sale. No royalties have been earned or paid under the Regeneron Agreement through September 30, 2026.

On January 28, 2022, Regeneron exercised its option to license the exclusive, worldwide rights to ADI-002, an allogeneic gamma delta CAR T cell therapy directed against Glypican-3, pursuant to the Regeneron Agreement. In conjunction with the exercise of the option, Regeneron paid an exercise fee of $20.0 million to the Company on January 28, 2022, and the Company completed the transfer of the associated license rights to Regeneron during the first quarter of 2022. The $20.0 million option exercise fee, plus $5.0 million of revenue recognized relating to the combined performance obligation, resulted in an aggregate of $25.0 million recorded as revenue for the year ended December 31, 2022. The Company's obligations under the combined performance obligation were completed during the year ended December 31, 2022.

Regeneron is responsible, at its sole cost, for all development, manufacturing and commercialization of ADI-002 and must pay the Company high single digit royalties as a percentage of any net sales of ADI-002 for a period commencing on the first commercial sale until the longer of (i) the expiration or invalidity of the licensed patent rights or (ii) a low double digit amount of years from first commercial sale.

Twist Bioscience

In March 2021, the Company entered into an Antibody Discovery Agreement (the Twist Agreement) with Twist Bioscience Corporation (Twist). Under the terms of the Twist Agreement, Twist will utilize its proprietary platform technology to assist the Company with the discovery of novel antibodies related to target antigens selected by the Company. The Company maintains the sole and exclusive rights to any program antibodies discovered under the Twist Agreement and has the right to patent, assign, license or transfer any work product under the agreement. Furthermore, the Company has the right to sublicense its rights to program antibodies to third parties. The Company may terminate the Twist Agreement at any time, with or without cause, upon a specified period advance written notice.

Per the terms of the agreement, the Company will pay Twist an upfront, non-refundable project initiation fee, a technology access fee, as well as a project fee for each project entered into under the agreement. Additionally, the Company will pay fees for development and regulatory milestones in the tens of millions of dollars and low single digit royalties on net sales to Twist for programs initiated under the agreement. In November 2022, the Company entered into an amendment to the Twist Agreement (the Twist Amendment). The Twist Amendment updates the language associated with Twist's audit rights as well as the amounts associated with technology access fees.

On a cumulative basis as of September 30, 2026, the Company has incurred and expensed $1.1 million related to project initiation fees, technology access fees and projects fees as research and development expense related to this agreement.

CRISPR

On May 16, 2023, the Company entered into a license and collaboration agreement with CRISPR Therapeutics AG (CRISPR Agreement) to non-exclusively license CRISPR's gene editing technology (CRISPR Technology) for use in up to a specified number of gamma delta licensed products. CRISPR also had an option to co-develop and co-commercialize a future gamma delta product (the Option Product). Additionally, the parties agreed on prostate-specific membrane antigen (PSMA) as a collaboration target that the Company would develop an Option Product against. CRISPR had opt-in rights to participate

in a 50/50 cost and profit split for the Option Product. If CRISPR had elected to opt-in, the Option Product would have been designated a collaboration product. Because CRISPR elected to not opt-in, the Option Product is a licensed product. The Company will lead and be primarily responsible for the development, manufacturing, and commercialization of the Collaboration Product in accordance with plans agreed upon by both parties.

For each licensed product, the Company will retain worldwide rights and may be required to make potential future payments based on the achievement of development and regulatory approval milestones totaling low double digit million dollars for each non-collaboration product, sales milestones totaling low double digit million dollars for each non-collaboration product, and tiered royalties up to low-single digit percentages on net product sales of such product. Unless earlier terminated, the term of the CRISPR Agreement will terminate (i) on a country-by-country basis with respect to each licensed product until the end of the last royalty term in such country for such licensed product and (ii) when a party opts out for collaboration products.

As of September 30, 2026, the Company has not paid any amounts nor are any amounts owed by the Company under the CRISPR Agreement, and no milestones have been achieved.

City of Hope

On July 9, 2024, City of Hope (COH) and the Company entered into a license agreement (COH Agreement) under which COH granted the Company a non-exclusive, worldwide license to patent rights related to its membrane-bound IL12 technology for use in gamma delta T cell products (Licensed Products). The Company may sublicense Licensed Products through multiple tiers. Unless earlier terminated, the term of the COH Agreement continues, on a country-by-country and Licensed Product-by-Licensed Product basis, until the royalty expiration date for each Licensed Product in each country. The Company may terminate the COH Agreement at any time, with or without cause, upon advance written notice.

As consideration for the license, the Company may pay fees for development and regulatory milestones that together total in the single digit millions of dollars and sales milestones in the low-to-mid double digit millions of dollars. Additionally, the Company will pay low single digit percentage royalties on net sales to COH for licensed products covered under the COH Agreement. The Company will pay COH a portion of all consideration received for sublicensing a Licensed Product, ranging from low double digit percentage to a low single digit percentage, such percentage decreasing as development advances for the Licensed Product.

As of September 30, 2026, the Company has incurred no payments under the COH agreement.

9. Commitments and Contingencies

Leases

The Company has operating leases for office and laboratory space in Redwood City, California and the Company has one finance lease for lab instruments.

Redwood City

In 2018, Adicet Therapeutics executed a non-cancelable lease agreement, as amended in 2022, pursuant to which the Company leases office and laboratory facility at 1000 Bridge Parkway and a portion of 1200 Bridge Parkway in Redwood City, California (the Redwood City Lease).

On January 9, 2023, Adicet Therapeutics entered into a third lease amendment with Westport Office Park, LLC (the Third Amendment). The Third Amendment further amends the Redwood City Lease and increases the tenant improvement allowance as of January 1, 2023 by an additional $3.0 million. The Company fully utilized the allowance for the continued buildout of office and laboratory space at 1000 Bridge Parkway in 2023. Per the terms of this amendment, this additional allowance will be repaid through equal monthly payments of principal amortization and interest on a monthly basis over the

term of the lease at an interest rate of eight percent (8%) per annum. The Company received the allowance on February 21, 2023 and increased the operating lease liability accordingly.

On August 7, 2023, Adicet Therapeutics entered into a fourth lease amendment with Westport Office Park, LLC (the Fourth Amendment). The Fourth Amendment amends the period over which the tenant improvement allowance received in the Third Amendment will be amortized and identifies the monthly amortization payable by the Company.

On November 19, 2025, Adicet Therapeutics entered into a fifth lease amendment with Westport Office Park, LLC (the Fifth Amendment). The Fifth Amendment acknowledges that the portion of the Redwood City Lease related to 1200 Bridge Parkway expired on June 30, 2025.

Boston

In 2018, the Company entered into a lease agreement, as amended in 2019, for office space at 500 Boylston St, Boston, Massachusetts (500 Boylston Lease). Under the terms of the 500 Boylston Lease, the Company was permitted to assign, sublease or transfer this lease, with the consent of the landlord. The lease expired on July 30, 2026 per its terms.

On July 19, 2021, the Company entered into a sublease agreement with RFS OPCO LLC (Sublessee), whereby the Company agreed to sublease to Sublessee all of the 9,501 rentable square feet of 500 Boylston St. The sublease agreement expired on July 30, 2026 per its terms.

The future minimum lease payments under all non-cancelable lease obligations as of September 30, 2026 were as follows (in thousands):

	Operating Leases	Finance Leases
2026	$ 921	$ —
2027	3,714	250
2028	3,808	250
2029	3,906	250
2030	662	250
2031 and thereafter	—	—
Total undiscounted lease payments	13,011	1,000
Less: imputed interest	(1,717)	(194)
Total lease liability	11,294	806
Less: current portion	(2,673)	(174)
Lease liability, net of current maturities	$ 8,621	$ 632

The following table presents the lease cost and information related to the lease right-of-use assets, net and lease liabilities for the quarter ended September 30, 2026 (in thousands):

	Three Months Ended September 30, 2026
Lease Cost	
Operating lease cost	$ 810
Short-term lease cost	34
Finance lease cost:	
Amortization of right-of-use assets	55
Interest on lease liabilities	23
Sublease income	(64)
Total lease cost	$ 858
Other Information	
Operating cash flows used for lease liabilities	$ 4,337
Financing cash flows used for finance lease liabilities	—
Weighted-average remaining lease term - operating leases (in years)	3.4
Weighted-average remaining lease term - finance leases (in years)	3.9
Weighted-average discount rate - operating leases	6.90%
Weighted-average discount rate - finance leases	10.00%

For the nine months ended September 30, 2026, the Company recognized $2.7 million and $0.1 million in operating lease and short-term lease costs, respectively. Additionally, for the nine months ended September 30, 2026, the Company recognized $0.4 million in sublease income.

For the nine months ended September 30, 2026, the Company recognized less than $0.2 million in reduction of right-of-use assets and interest on lease liabilities for the finance lease.

The Company maintains letters of credit in connection with the Company's office leases in Redwood City, CA. Refer to Note 16 Restricted Cash for additional information about these letters of credit.

Vendor Dispute

The Company is involved in an ordinary course proceeding arising from a dispute with a former vendor over certain service-related charges. Due to the inherent uncertainties of matter, the Company is unable to predict the outcome of the matter at this time. Furthermore, the Company cannot reasonably estimate the possible loss or range of loss, if any, that may result from this matter. However, in the event of unexpected further developments, it is possible that the ultimate resolution of this matter, if unfavorable, may have an adverse impact on our business, financial condition, results of operations or liquidity.

10. Stockholders' Equity

Common Stock

The Company's Restated Certificate of Incorporation, which became effective as of June 6, 2024, authorized the Company to issue 300,000,000 shares of common stock, par value $0.0001 per share.

Common stockholders are entitled to dividends if and when declared by the board of directors of the Company subject to the prior rights of the preferred stockholders. As of September 30, 2026, no dividends on common stock had been declared by the board of directors.

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

	September 30, 2026	December 31, 2025
Stock options and restricted stock units available for future grant	355,958	682,713
Stock options issued and outstanding	1,594,979	763,464
Unvested restricted stock units	65,461	46,842
Common stock warrants issued and outstanding	1,402,833	1,152,833
Total common stock reserved	3,419,231	2,645,852

On January 22, 2024, the Company entered into the Underwriting Agreement with Jefferies and Guggenheim, as representatives of the 2024 Underwriters, related to the Offering of 2,023,729 shares of common stock, which included 332,812 shares sold and issued upon the exercise in full by the 2024 Underwriters of their option to purchase additional shares of common stock, and, in lieu of common stock to certain investors, pre-funded warrants to purchase 527,833 shares of common stock. The pre-funded warrants were sold at a public offering price of $38.3984 per pre-funded warrant, which represents the per share public offering price of each share of common stock minus the $0.0016 per share exercise price for each pre-funded warrant. The pre-funded warrants do not have an expiration date and are exercisable at any time. The pre-funded warrants are classified as equity within the Company's consolidated balance sheet. The Company received net proceeds from the Offering, after deducting the underwriting discount and commissions and other offering expenses, of approximately $91.7 million. The Company may receive nominal proceeds, if any, from the exercise of the pre-funded warrants.

On October 7, 2025, the Company entered into the 2025 Underwriting Agreement with Jefferies and Guggenheim, as representatives of the 2025 Underwriters, related to the 2025 Offering of 4,375,062 shares of common stock, and, in lieu of common stock to an investor, pre-funded warrants to purchase 625,000 shares of common stock. The 2025 Shares were sold at a price of $16.00 per share and the 2025 Pre-Funded Warrants were sold at a price of $15.9984 per underlying share, which represents the per share offering price of each share of common stock minus the $0.0016 per share exercise price for each

pre-funded warrant. The pre-funded warrants do not have an expiration date and are exercisable at any time. The pre-funded warrants are classified as equity within the Company's consolidated balance sheet. The Company received net proceeds from the 2025 Offering, after deducting the underwriting discount and commissions and other offering expenses, of approximately $74.8 million. The Company may receive nominal proceeds, if any, from the exercise of the 2025 Pre-Funded Warrants.

In April 2026, the Company entered into an exchange agreement with RA Capital Management, L.P. and RA Capital Healthcare Fund, L.P. (together, RA Capital), pursuant to which RA Capital exchanged 250,000 shares of the Company's common stock, par value $0.0001 per share, for a pre-funded warrant to acquire 250,000 shares of the Company's common stock. The 250,000 shares of common stock subject to the exchange agreements were retired on the date of the exchange.

The pre-funded warrant has an exercise price of $0.0001 per underlying share. The pre-funded warrant is exercisable from the date of issuance by means of a cashless exercise. Under the pre-funded warrant, the Company may not effect the exercise of the pre-funded warrant, and a holder will not be entitled to exercise any portion of the pre-funded warrant that, upon giving effect to such exercise, would cause: (i) the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates) to exceed 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of the Company's securities beneficially owned by the holder (together with its affiliates) to exceed 9.99% of the combined voting power of all of the Company's securities then outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrant, unless such percentage is increased upon at least 61 days' prior notice, but not in excess of 19.99%.

The following provides a roll forward of outstanding pre-funded warrants to purchase common stock as of September 30, 2026:

Issuance Date	Number of Shares of Common Stock Issuable	Weighted Average Exercise Price
Outstanding, December 31, 2025	1,152,833	$ 0.0016
Warrants issued	250,000	0.0001
Warrants exercised	—	—
Warrants forfeited	—	—
Outstanding, September 30, 2026	1,402,833	$ 0.0013

11. Stock-based Compensation

Stock-based Compensation Expense

Total stock-based compensation expense recognized was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 770	$ 1,269	$ 2,477	$ 4,496
General and administrative	736	1,260	1,773	4,121
Total stock-based compensation	$ 1,506	$ 2,529	$ 4,250	$ 8,617

Stock Options

In June 2026, the Company granted 110,000 stock options to certain employees with service vesting conditions that contain performance-based acceleration clauses. Vesting is based on continued service and may accelerate upon the achievement of specified milestone events. The Company concluded that the probability of achieving each of the milestones was not probable as of the grant date and remained not probable as of September 30, 2026. The Company will recognize the

compensation expense for these options based on the graded vesting method over the service period and has recognized $0.1 million and $0.2 million of related expense during the three and nine months ended September 30, 2026, respectively.

A summary of stock option activity for the nine months ended September 30, 2026 is set forth below:

	Number of Shares Underlying Outstanding Options	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2025	763,464	$ 40.23	8.0	$ —
Options granted	1,042,296	$ 7.10		
Options exercised	(257)	$ 7.04		
Options forfeited or cancelled	(210,524)	$ 30.23		
Outstanding, September 30, 2026	1,594,979	$ 19.91	8.6	$ 226
Options exercisable, September 30, 2026	554,361	$ 38.56	7.4	$ 30
Vested and expected to vest, September 30, 2026	1,594,979	$ 19.91	8.6	$ 226

The assumptions used in the Black-Scholes option-pricing model to calculate stock-based compensation are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Fair value of common stock	$7.14 - $9.43	$11.20 - $12.96	$6.81 - $9.43	$8.48 - $14.40
Expected term (years)	5.33 - 6.05	5.77 - 6.07	5.33 - 6.08	5.5 - 6.08
Volatility	90.01% - 91.94%	92.28% - 93.53%	90.01% - 92.0%	88.28% - 93.97%
Risk free rates	4.39% - 5.14%	3.81% - 4.0%	3.62% - 5.14%	3.81% - 4.43%
Dividend rate	0.0%	0.0%	0.0%	0.0%

Restricted Stock Units (RSUs)

The summary of RSU activity and related information for the nine months ended September 30, 2026 is set forth below:

	Number of Units Outstanding	Weighted Average Grant Date Fair Value
Outstanding, December 31, 2025	46,842	$ 37.81
RSUs granted	50,138	$ 7.04
RSUs vested	(22,282)	$ 53.83
RSUs forfeited	(9,237)	$ 15.30
Outstanding, September 30, 2026	65,461	$ 11.98

Option repricing

On August 8, 2023, the board of directors approved a stock option repricing (the Option Repricing) effective on August 14, 2023 (the Effective Date) in accordance with the terms of the Company's 2015 Stock Incentive Plan (the 2015 Plan) and Second Amended and Restated 2018 Stock Option and Incentive Plan (the 2018 Plan, and together with the 2015 Plan, the Plans). Pursuant to the Option Repricing, the exercise price of each stock option previously granted under the Plans, totaling 401,994 options, was amended to reduce the exercise price of such options to $34.24 per share, the closing price of the Company's common stock on the Nasdaq Global Market on the Effective Date, as updated to reflect the reverse stock split.

The repriced options otherwise retained their existing terms and conditions as set forth in the Plans and applicable award agreements. The stock option modification resulted in $4.6 million of incremental compensation cost, which was calculated using the Black-Scholes option-pricing model. Of the incremental compensation cost, $0.1 and $0.3 million was recognized in the nine months ended September 30, 2026 and 2025, respectively. The remaining incremental compensation cost of less than $0.1 million, net of the reversal of expense related to employee terminations prior to August 14, 2024, will be recognized on the straight-line basis over the remaining vesting period of the repriced options. The incremental cost is included in general and administrative expense and research and development expense on the consolidated statements of operations.

Effective August 21, 2024, the board of directors approved a rescission of the Option Repricing for certain non-employee directors of the Company. All of the affected stock options have been reverted to their original exercise price as established at the time of the grant. The Company will continue to recognize the incremental fair value from the Option Repricing for the impacted options. The compensation expense associated with the Option Repricing for these options was not material.

12. Net Loss per Share

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net loss - basic and diluted	$ (18,878)	$ (26,856)	$ (60,480)	$ (86,287)
Weighted-average shares used in computing net loss per share, basic and diluted	10,745,696	5,692,874	10,753,547	5,713,216
Net loss per share, basic and diluted	$ (1.76)	$ (4.72)	$ (5.62)	$ (15.10)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the period presented because including them would have been antidilutive:

	As of September 30,	
	2026	2025
Options to purchase common stock	1,594,979	1,096,448
Unvested restricted stock units	65,461	47,486
Total	1,660,440	1,143,934

13. Income Taxes

The Company recognized less than $0.1 million and $0.1 million of income tax expense during the three and nine months ended September 30, 2026, respectively. The Company recognized no income tax expense during the three and nine months ended September 30, 2025. The Company maintains a full valuation allowance against its deferred tax assets due to the Company's history of losses as of September 30, 2026.

On July 4, 2025, the One Big Beautiful Bill Act (OBBBA), which includes a broad range of tax reform provisions, was signed into law in the United States and we continue to assess its impact. The OBBBA is not currently expected to materially impact the Company's effective tax rate or cash flows in the current fiscal year.

14. Related Party

As of the latest public filing made by Regeneron, Regeneron owned 60,511 shares of the Company's common stock. Regeneron became a related party in July 2019 as a result of Series B redeemable convertible preferred stock financing which was subsequently converted into common stock. For the three and nine months ended September 30, 2026, the Company recorded no revenue from the Regeneron Agreement. See *Note 8* for a discussion of the Regeneron Agreement.

15. Segment Reporting

The Company's operations are organized and reported as a single reportable segment, which includes all activities related to the discovery, development, and commercialization of allogeneic gamma delta T cell therapies for autoimmune diseases and cancer. The Company's Chief Executive Officer, who is the chief operating decision maker (CODM), reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. This presentation is consistent with how the Company's CODM assesses the performance of the Company and makes operating decisions on a consolidated basis. The CODM assesses performance and decides how to allocate resources based on consolidated net loss that also is reported on the consolidated statements of operations and comprehensive loss as net loss. The CODM uses consolidated net loss to monitor budget versus actual results, assess cash runway, and benchmark against the Company's competitors. The measure of segment assets is reported on the consolidated balance sheets as total assets. The Company's assets are primarily held in the United States.

The following table sets forth the Company's segment information (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
External program expenses for product candidates				
Prula-cel	$ 1,006	$ 1,102	$ 5,725	$ 8,954
ADI-270	(13)	3,444	165	8,914
ADI-212	1,156	646	3,330	1,415
Total external program expenses for product candidates	2,149	5,192	9,220	19,283
Non-program specific expenses[(1)]	2,938	3,636	9,008	8,400
Personnel-related expenses (including non-cash stock-based compensation)[(2)]	7,882	12,593	26,524	40,226
Depreciation	1,039	1,573	3,580	4,908
Professional services and consulting fees	2,583	1,667	5,910	6,087
Facilities and infrastructure expenses	1,794	1,780	5,376	6,385
Other segment expense[(3)]	1,411	1,511	4,049	4,939
Interest income	(972)	(1,172)	(3,482)	(4,253)
Other expense, net[(4)]	53	76	151	312
Income tax provision	1	—	144	—
Segment net loss	$ 18,878	$ 26,856	$ 60,480	$ 86,287

(1) Relates to platform research and development expenses which are not attributed to specific programs.

(2) Relates to personnel-related expenses including non-cash stock-based compensation for the three months ended September 30, 2026 and 2025 of $1.5 and $2.5 million, respectively, and the nine months ended September 30, 2026 and 2025 of $4.3 million and $8.6 million, respectively.

(3) Relates to other expenses primarily for software subscriptions and licenses, office expenses, travel and entertainment, director compensation and recruiting fees.

(4) Consists of interest expense and other expenses.

16. Restricted Cash

As of September 30, 2026, the Company maintained letters of credit of $2.6 million, which are collateralized with bank accounts at financial institutions in accordance with the agreements. The letters of credit are included within restricted cash on the Company's consolidated balance sheets. Total restricted cash as of September 30, 2026 and December 31, 2025 consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Redwood City, CA lease[(1)]	$ 2,274	$ 2,306
Boston, MA lease	—	266
Corporate credit card services	300	300
Total	$ 2,574	$ 2,872

(1) Includes the Company's lease at 1000 Bridge Parkway and 1200 Bridge Parkway.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related footnotes included in our Annual Report on Form 10-K for the year ended December 31, 2025. This discussion and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" included elsewhere in this Quarterly Report on Form 10-Q, as supplemented by our subsequent filings with the SEC.

Overview

We are a clinical stage biotechnology company discovering and developing a broad pipeline of allogeneic gamma delta T cell therapies, engineered with chimeric antigen receptors (CARs) alongside differentiated in vivo CAR-T therapies with the potential to redefine treatment across autoimmune diseases, hematologic malignancies and solid tumors.

Our approach to activate, engineer and manufacture allogeneic gamma delta T cell product candidates derived from the peripheral blood cells of unrelated donors allows us to generate new product candidates in a rapid and cost-efficient manner. Our allogeneic "off-the-shelf" manufacturing process is designed to allow product from unrelated donors to be stored and sold on demand to treat patients without inducing a graft versus host immune response. This is in contrast to products based on alpha beta T cells, which either must be manufactured for each patient from his or her own T cells, or require significant gene editing to manufacture if the T cells are derived from donors that are unrelated to the patient.

Our lead product candidate, prula-cel, a first-in-class allogeneic gamma delta T cell therapy expressing a CAR targeting CD20, is being developed for the potential treatment of autoimmune diseases. We are also pursuing ADI-212, a next-generation gene-edited and armored clinical candidate designed to target prostate-specific membrane antigen (PSMA). ADI-212 is engineered to express a novel CAR binder designed to support enhanced tolerability and tumor-specific recognition. It integrates membrane-tethered IL-12 armoring and CRISPR/Cas9 mediated disruption of subunit 12 of the mediator complex (MED12) to enhance potency in solid tumors and to deliver multiple anti-tumor mechanisms of action to the tumor microenvironment. We aim to submit a new regulatory submission, such as an Investigational New Drug (IND) application or equivalent every 12-18 months.

Prula-cel

We are advancing patient enrollment in our Phase 1 program of prula-cel across multiple autoimmune diseases. In December 2023, the U.S. Food and Drug Administration (FDA) cleared our IND application for prula-cel in lupus nephritis (LN) and has subsequently authorized the evaluation of prula-cel in systemic lupus erythematosus (SLE), systemic sclerosis (SSc), anti-neutrophil cytoplasmic autoantibody associated vasculitis (AAV), idiopathic inflammatory myopathies (IIM) and stiff person syndrome (SPS) within the Company's Phase 1 clinical trial. In November 2025, we reached alignment with the FDA to allow LN and SLE patients to be dosed with prula-cel in the outpatient setting in ongoing and future clinical trials. Prula-cel has received Fast Track Designation by the FDA for the potential treatment of relapsed/refractory class III or class IV LN, refractory SLE with extrarenal involvement and for SSc. In September 2026, the Company prioritized development of prula-cel toward potential pivotal studies in systemic lupus erythematosus (SLE), including both lupus nephritis and extra-renal SLE.

We believe the favorable safety profile, cellular kinetics and B cell depletion in peripheral blood and secondary lymphoid tissue demonstrated with prula-cel clinical experience to date is favorable for development in autoimmune diseases. We believe the potential market opportunity for prula-cel in B cell mediated autoimmune diseases is substantial based on the prevalence in the U.S., EU5, China and Japan of greater than 1.7 million patients with autoimmune diseases where CAR-T cell therapy has demonstrated clinical proof-of-concept, including SLE (which includes LN), SSc, IIM and SPS.

In September 2026, we announced positive safety and efficacy data from 22 efficacy evaluable patients (16 LN and 6 extra-renal SLE patients) dosed in our Phase 1 trial of prula-cel in autoimmune diseases, as of the August 28, 2026 data cut-off date. All patients had at least 6 months of follow-up, and 13 patients had at least 12 months of follow-up. Based on these findings, the Company has initiated start-up activities for a pivotal study in LN. The single-arm study is expected to enroll a double-digit number of patients, with complete renal response at 12 months as the primary efficacy endpoint. Given the high

Definition of Remission in Systemic Lupus Erythematosus (DORIS) rates reported in the September 2026 clinical data update, the Company plans to engage with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2026 regarding the potential expansion of its pivotal development program to include lupus patients without nephritis. The Company expects to provide an update on these discussions, as well as additional clinical data from approximately 22 patients with at least 12 months of follow-up, in the first quarter of 2027. In addition, the Company expects to report clinical data evaluating prula-cel in SSc in the second quarter of 2027.

ADI-212

We are advancing ADI-212, a next-generation gene-edited and armored clinical candidate designed to target prostate-specific membrane antigen. ADI-212 is engineered to express a novel CAR binder designed to support enhanced tolerability and tumor-specific recognition. It integrates membrane-tethered IL-12 (mbIL-12) armoring and CRISPR/Cas9 mediated disruption of subunit 12 of the mediator complex (MED12) to enhance potency in solid tumors and deliver multiple anti-tumor mechanisms of action within the tumor microenvironment. In August 2026, the FDA cleared our IND application for ADI-212 in metastatic castration-resistant prostate cancer (mCRPC), followed by the granting of Fast Track Designation in September 2026. Phase 1 startup activities are underway, with patient enrollment in mCRPC anticipated in the first quarter of 2027. We believe the potential market opportunity for ADI-212 in mCRPC is significant based on the prevalence in the U.S., EU5, China and Japan of approximately 75,000 patients with second or third line advanced disease.

In Vivo CAR-T Program and Pipeline

The Company is developing a differentiated in vivo CAR-T platform designed to achieve highly efficient, selective T-cell transduction through proprietary cell-specific delivery technologies, including novel homing and VSV-G (Vesicular Stomatitis Virus Glycoprotein G) fusogen technologies. The Company's clinical pipeline includes programs targeting multiple myeloma, non-Hodgkin's lymphoma (NHL) and solid tumors, with differentiated CAR designs and biology-modifying technologies intended to enhance potency, efficacy and durability. The Company plans to initiate the first clinical study from its in-vivo CAR-T program in the second half of 2027.

Financial Operations Overview

Revenue

We have no products approved for commercial sale and do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for our product candidates, which we expect will not be for at least several years, if ever.

Expenses

Research and Development

Research and development expenses, which consist primarily of costs incurred in connection with the development of our product candidates, are expensed as incurred. Research and development expenses consist primarily of:

- employee related costs, including salaries, benefits and stock-based compensation expenses for research and development employees;
- costs incurred under agreements with consultants, contract development and manufacturing organizations (CDMOs) and contract research organizations (CROs);
- lab materials, supplies and maintenance of equipment used for research and development activities; and
- allocated facility-related costs, such as rent, utilities, insurance, repairs and maintenance, depreciation and amortization, information technology costs and general support services.

We allocate our external costs by product candidate. We do not allocate our internal costs by product candidate as a significant amount of internal research and development expenses are not tracked by product candidate, and we believe the allocation of such costs would be arbitrary and would not provide a meaningful assessment as we have used our employee and infrastructure resources across multiple product candidate research and development programs.

We are focusing substantially all of our resources on the development of our product candidates. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates. The duration, costs, and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress and expense of clinical trials and other research and development activities;
- clinical trial results;
- uncertainties in clinical trial enrollment rate or design;
- significant and changing government regulation;
- the timing and receipt of any regulatory approvals;
- the FDA's or other regulatory authority's influence on clinical trial design;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- expenses incurred in connection with our license and collaboration agreements, including license payments, program expenses and milestone obligations payable by us;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for product candidates;
- continued applicable safety profiles of the products following approval; and
- retention of key research and development personnel.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans.

Adequate funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development programs and clinical trials or we may also be required to sell or license to other rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves. If we are required to enter into collaborations and other arrangements to supplement our funds, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or may have other terms that are not favorable to us or our stockholders, which could materially affect our business and financial condition.

General and Administrative

General and administrative expenses consist principally of payroll and personnel expenses, including salaries and bonuses, benefits and stock-based compensation expenses, professional fees for legal, consulting, accounting and tax services, allocated overhead expenses, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase for the foreseeable future due to expenses related to operating as a public company, including expenses related to personnel costs, expanded infrastructure and higher consulting, legal and accounting services costs associated with complying with the applicable Nasdaq and SEC requirements, investor relations costs and director and officer insurance premiums.

Interest Income

Interest income consists primarily of interest earned on our cash, cash equivalents, restricted cash and short-term investments in treasury securities.

Interest Expense

Interest expense consists primarily of interest on finance lease liabilities.

Other Expense, Net

Other expense, net primarily consists of state franchise and capital taxes not related to income.

Results of Operations

Comparison of the Three Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the periods indicated (in thousands, except percentages):

	Three months ended September 30,			
	2026	2025	Change	% Change
Operating expenses				
Research and development	$ 15,626	$ 22,853	$ (7,227)	(32%)
General and administrative	4,170	5,099	(929)	(18%)
Total operating expenses	19,796	27,952	(8,156)	(29%)
Loss from operations	(19,796)	(27,952)	8,156	29%
Interest income	972	1,172	(200)	(17%)
Interest expense	(23)	(12)	(11)	92%
Other expense, net	(30)	(64)	34	53%
Loss before income tax benefit	(18,877)	(26,856)	7,979	30%
Income tax provision	(1)	—	(1)	—
Net loss	$ (18,878)	$ (26,856)	$ 7,978	30%

Research and development

	Three months ended September 30,	
	2026	2025
Payroll and personnel expenses(1)	$ 5,739	$ 9,411
Costs incurred under agreements with consultants, CDMOs, and CROs	2,988	5,654
Lab materials, supplies and maintenance of equipment used for research and development activities	1,596	2,349
Other research and development expenses(2)	5,303	5,439
Total research and development expenses	$ 15,626	$ 22,853

(1) Employee related costs, including salaries, benefits, bonuses, and stock-based compensation expenses for research and development employees.

(2) Professional fees and allocated facility-related costs, such as rent, utilities, insurance, repairs and maintenance, depreciation and amortization, information technology costs and general support services.

Research and development expenses decreased by $7.2 million, or 32%, during the three months ended September 30, 2026 as compared to the same period in 2025. The decrease in research and development expenses was primarily due to a $3.7 million decrease in payroll and personnel expenses due to lower headcount, a $2.7 million decrease related to lower CRO expenses due to no new enrollment of patients, a $0.4 million decrease in allocated facility-related expenses, and a $0.8 million decrease in expenses related to lab supplies and materials. The decrease was partially offset by a $0.3 million increase in professional fees.

General and administrative

General and administrative expenses decreased by $0.9 million, or 18%, during the three months ended September 30, 2026 as compared to the same period in 2025. The decrease in general and administrative expenses was due to a decrease in payroll and personnel related expenses of $1.0 million primarily related to a decrease in stock-based compensation and lower headcount. The decrease was partially offset by a $0.1 million increase in professional fees and allocated facility-related expenses.

Interest income

Interest income decreased by $0.2 million, or 17% during the three months ended September 30, 2026 as compared to the same period in 2025, which was primarily due to lower interest rates and lower cash balances for the period.

Other expense, net

Other expense, net decreased by less than $0.1 million, or 53%, during the three months ended September 30, 2026 as compared to the same period in 2025. This was due to a decrease in realized losses related to foreign exchange rates.

Comparison of the Nine Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the periods indicated (in thousands, except percentages):

	Nine Months Ended September 30,			
	2026	2025	Change	% Change
Operating expenses				
Research and development	$ 51,562	$ 74,091	$ (22,529)	(30%)
General and administrative	12,105	16,137	(4,032)	(25%)
Total operating expenses	63,667	90,228	(26,561)	(29%)
Loss from operations	(63,667)	(90,228)	26,561	29%
Interest income	3,482	4,253	(771)	(18%)
Interest expense	(68)	(12)	(56)	467%
Other expense, net	(83)	(300)	217	72%
Loss before income tax benefit	(60,336)	(86,287)	25,951	30%
Income tax provision	(144)	—	(144)	—
Net loss	$ (60,480)	$ (86,287)	$ 25,807	30%

Research and development

	Nine Months Ended September 30,	
	2026	2025
Payroll and personnel expenses(1)	$ 19,827	$ 29,948
Costs incurred under agreements with consultants, CDMOs, and CROs	10,403	17,558
Lab materials, supplies and maintenance of equipment used for research and development activities	5,763	8,693
Other research and development expenses(2)	15,569	17,892
Total research and development expenses	$ 51,562	$ 74,091

(1) Employee related costs, including salaries, benefits, bonuses, and stock-based compensation expenses for research and development employees.

(2) Professional fees and allocated facility-related costs, such as rent, utilities, insurance, repairs and maintenance, depreciation and amortization, information technology costs and general support services.

Research and development expenses decreased by $22.5 million, or 30%, during the nine months ended September 30, 2026 as compared to the same period in 2025. The decrease in research and development expenses was primarily due to a $10.1 million decrease in payroll and personnel expenses due to lower headcount, a $7.2 million decrease related to lower CRO expenses due to no new enrollment of patients, a $2.9 million decrease in expenses related to lab supplies and materials and a $2.8 million decrease in allocated facility-related expenses. The decrease was partially offset by a $0.5 million increase in professional fees.

General and administrative

General and administrative expenses decreased by $4.0 million, or 25%, during the nine months ended September 30, 2026 as compared to the same period in 2025. The decrease in general and administrative expenses was due to a decrease in payroll and personnel related expenses of $3.3 million primarily related to a decrease in stock-based compensation and lower headcount and a $0.9 million decrease in professional fees. The decrease was partially offset by a $0.2 million increase in allocated facility-related expenses.

Interest income

Interest income decreased by $0.8 million, or 18% during the nine months ended September 30, 2026 as compared to the same period in 2025, which was primarily due to lower interest rates and lower cash balances for the period.

Other expense, net

Other expense, net decreased by $0.2 million, or 72%, during the nine months ended September 30, 2026 as compared to the same period in 2025. This was due to losses from disposals of property and equipment recognized in 2025.

Liquidity and Capital Resources

Sources of Liquidity

We have historically funded our operations primarily through a collaboration and licensing arrangement, public and private placements of equity securities and debt, and cash received in our merger with resTORbio, Inc.

In January 2024, we raised aggregate net proceeds of approximately $19.3 million through the JonesTrading ATM Program. In March 2024, we terminated the JonesTrading ATM Program and entered into the Jefferies ATM Program. As of September 30, 2026, no shares of common stock have been sold through the Jefferies ATM Program.

On January 22, 2024, we entered into an underwriting agreement (the Underwriting Agreement) with Jefferies LLC (Jefferies) and Guggenheim Securities, LLC (Guggenheim), as representatives of the underwriters, related to an underwritten public offering (the Offering) of shares of our common stock and, in lieu of common stock to certain investors, pre-funded warrants to purchase shares of our common stock. We received net proceeds from the Offering, after deducting the underwriting discount and commissions and other estimated offering expenses, of approximately $91.7 million. We may receive nominal proceeds, if any, from the exercise of the pre-funded warrants.

On October 7, 2025, we entered into an underwriting agreement with Jefferies and Guggenheim, as representatives of the underwriters, related to an underwritten registered direct offering (the 2025 Offering) of shares of our common stock, and, in lieu of our common stock to an investor, pre-funded warrants to purchase shares of our common stock. We received net proceeds from the 2025 Offering, after deducting the underwriting discount and commissions and other estimated offering expenses, of approximately $74.8 million. We may receive nominal proceeds, if any, from the exercise of the 2025 Pre-Funded Warrants.

Future Funding Requirements

We have incurred losses since inception and have incurred losses of $60.5 million and $86.3 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $675.2 million.

As of September 30, 2026, we had cash, cash equivalents, and short-term investments in treasury securities of $100.9 million. Based on our current operating plan, we believe that substantial doubt exists about our ability to continue as a going concern for at least twelve months following the filing of this Quarterly Report on Form 10-Q, and we will need to obtain additional funding.

All of our revenue to date has been generated from a collaboration and license agreement (the Regeneron Agreement) with Regeneron Pharmaceuticals, Inc. (Regeneron). We do not expect to generate any significant product revenue until we obtain regulatory approval of and commercialize any of our product candidates or enter into additional collaborative agreements with third parties, and we do not know when, or if, either will occur. We expect to continue to incur significant

losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. We anticipate that we will need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the timing, number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of operational, financial and management systems;
- the impact of potential health emergencies on United States and global economic conditions that may impact our ability to access capital on terms anticipated, or at all; and
- the post-merger costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. Adequate funding may not be available to us on acceptable terms or at all.

Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials or we may also be required to sell or license to other rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves. If we are required to enter into collaborations and other arrangements to supplement our funds, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or may have other terms that are not favorable to us or our stockholders, which could materially affect our business and financial condition.

See the section of this Quarterly Report on Form 10-Q titled "*Risk Factors*" for additional risks associated with our substantial capital requirements.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of our cash and cash equivalents for each of the periods presented below (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash provided by (used in):		
Operating activities	$ (59,233)	$ (74,337)
Investing activities	47,134	46,928
Financing activities	(6)	13
Net decrease in cash, cash equivalents and restricted cash	$ (12,105)	$ (27,396)

Cash Flows from Operating Activities

Net cash used in operating activities was $59.2 million for the nine months ended September 30, 2026. Cash used in operating activities consisted of net loss partially offset by non-cash adjustments of $8.1 million, and a net decrease in operating assets and liabilities of $6.8 million. Non-cash items primarily included depreciation and amortization of $3.6 million, stock-based compensation expense of $4.3 million, non-cash lease expense of $2.2 million and a net amortization of premiums and accretion discounts on investments of $1.9 million. The net change in assets and liabilities was primarily due to a decrease in accounts payable of $2.0 million, a net decrease in accrued and other current and non-current liabilities of $2.0 million, a decrease in operating lease liability of $2.6 million, a decrease in prepaid expenses of $0.1 million and a decrease in other current assets of less than $0.1 million.

Net cash used in operating activities was $74.3 million for the nine months ended September 30, 2025. Cash used in operating activities consisted of net loss offset by non-cash adjustments of $13.1 million, and a net decrease in operating assets and liabilities of $1.2 million. Non-cash items primarily included depreciation and amortization of $4.9 million, stock-based compensation expense of $8.6 million, non-cash lease expense of $2.4 million and a net amortization of premiums and accretion discounts on investments of $2.9 million. The net change in assets and liabilities was primarily due to a net decrease in accrued and other current and non-current liabilities of less than $0.1 million and a decrease in operating lease liability of $2.7 million, offset by an increase in accounts payable of $0.7 million, an increase in prepaid expenses and other current assets of $0.5 million and an increase in other non-current assets of $0.3 million.

Cash Flows from Investing Activities

Net cash provided by investing activities was $47.1 million for the nine months ended September 30, 2026, which consisted of $108 million related to maturities of short-term treasury securities, net of $60.6 million of purchases of short-term treasury securities and $0.3 million of purchases of lab equipment and leasehold improvements for our Good Manufacturing Practice (GMP) cell processing suite at 1000 Bridge Parkway.

Net cash provided by investing activities was $46.9 million for the nine months ended September 30, 2025, which consisted of $110 million related to maturities of short-term treasury securities, net of $61.3 million purchases of short-term treasury securities and $1.7 million of purchases of lab equipment and leasehold improvements for our Good Manufacturing Practice (GMP) cell processing suite at 1000 Bridge Parkway.

Cash Flows from Financing Activities

Net cash used in financing activities was less than $0.1 million for the nine months ended September 30, 2026, which was primarily related to net proceeds from the issuance of common stock in connection with our employee stock purchase plan. This was partially offset by cash paid for taxes withheld on the net share settlement of equity awards and issuance costs related to exchange of common stock for pre-funded warrant.

Net cash provided by financing activities was less than $0.1 million for the nine months ended September 30, 2025, which included $0.3 million in net proceeds from the issuance of common stock in connection with our employee stock purchase plan. This was partially offset by $0.1 million cash paid for taxes withheld on the net share settlement of equity awards and $0.2 million cash paid for the principal payment on finance leases.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the reported amounts of revenues and expenses during the reported periods and related disclosures. These estimates and assumptions, including those related to accruals for CDMO, CRO and research and development expenses, and equity-based compensation are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. These critical estimates and assumptions are based on our historical experience, our observance of trends in the industry, and various other factors that are believed to be reasonable under the circumstances and form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from our estimates under different assumptions or conditions. A summary of our significant accounting policies is contained in Note 2 of our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. There have been no material changes in our critical accounting policies from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on March 12, 2026.

Smaller Reporting Company

We are a "smaller reporting company" as defined in the Exchange Act. As a smaller reporting company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable, in general, to public companies that are not smaller reporting companies. These provisions include (i) not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act of 2002, as amended; (ii) scaled executive compensation disclosures; and (iii) the option to provide only two years of audited financial statements, instead of three years.

We will continue to be a smaller reporting company for as long as we continue to have (i) less than $250 million in market value of our shares held by non-affiliates as of the last business day of our second fiscal quarter or (ii) less than $100 million of annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter and a market value of our shares held by non-affiliates of less than $700 million as of the last business day of our second fiscal quarter.

We may choose to take advantage of some but not all of these exemptions. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. We have elected to avail ourselves of the exemption for the delayed adoption of certain accounting standards and, therefore, are not subject to the same new or revised accounting standards as other public companies that are not smaller reporting companies.

Recently Issued and Adopted Accounting Pronouncements

See the section titled *"Summary of Significant Accounting Policies"* in Note 2 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

As of September 30, 2026, we had cash, cash equivalents and short-term investments in treasury securities of $100.9 million, which consisted of cash and funds invested in treasury securities and money market funds. Interest income is sensitive to general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material impact on our cash, cash equivalents and short-term investments in treasury securities, financial position, or results of operations.

Foreign Currency Exchange Risk

Our headquarters are located in the United States, where a majority of our general and administrative expenses and research and development costs are incurred in U.S. Dollars. As we grow our business, our results of operations and cash flows may be subject to fluctuations due to foreign currency exchange rates. To date, we do not believe foreign currency exchange rate fluctuations have had a significant impact on our results of operations for any periods presented herein.

Inflation Risk

Our assets are primarily monetary, consisting of cash, cash equivalents and short-term investments in treasury securities. Because of their liquidity, these assets are not directly affected by inflation. Since we intend to retain and continue to use our equipment, furniture, fixtures and office equipment, computer hardware and software and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. Inflation generally affects us by increasing our cost of labor, clinical trial and manufacturing costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three months ended September 30, 2026.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, such as this report, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to our management, including the Chief Executive Officer (CEO) and Chief Financial Officer (CFO), as appropriate to allow timely decisions regarding required disclosure. As of September 30, 2026, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) and concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. These limitations include the possibility of human error, the circumvention or overriding of the controls and procedures and reasonable resource constraints. In addition, because we have designed our system of controls based on certain assumptions, which we believe are reasonable, about the likelihood of future events, our system of controls may not achieve its desired purpose under all possible future conditions. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this report, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, our Annual Report on Form 10-K for the year ended December 31, 2025, and in other documents that we file with the U.S. Securities and Exchange Commission (SEC), in evaluating us and our business. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks facing us. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations.

The risk factors denoted with a "", if any, are newly added or have been materially updated from our Annual Report on Form 10-K for the year ended December 31, 2025.*

Risks Related to Our Business and Industry

Risks Related to Operating History

We have a limited operating history and face significant challenges and expenses as we build our capabilities.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We began operations in November 2014. We have a limited operating history upon which someone can evaluate our business and prospects and is subject to the risks inherent in any early stage company, including, among other things, risks that we may not be able to hire sufficient qualified personnel and establish operating controls and procedures. We currently do not have complete in-house resources to enable our gamma delta T cell platform. As we build our own capabilities, we expect to encounter risks and uncertainties frequently experienced by growing companies in new and rapidly evolving fields, including the risks and uncertainties described herein. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred net losses since our inception and anticipate that we will incur substantial net losses in the future.

We are an early clinical stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we will continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred net losses since our inception. To date, we have financed our operations primarily with proceeds from our license and collaboration agreements and the issuance and sale of our capital stock, including most recently net proceeds of approximately $74.8 million, after deducting the underwriting discount and commissions and other estimated offering expenses, from the sale of our common stock and pre-funded warrants in an underwritten registered direct offering in October 2025. For the three months ended September 30, 2026, we recorded net loss of $18.9 million. As of September 30, 2026, we had an accumulated deficit of $675.2 million.

We expect to incur significant expenditures for the foreseeable future, and we expect these expenditures to increase as we continue our research and development of, and seek regulatory approvals for, product candidates based on our gamma delta T cell platform, including prula-cel and ADI-212. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. In addition, certain of our existing license and collaboration agreements require cash payments upon the achievement of milestone events, royalties and profit-sharing, or other cash payments. These payment obligations, in addition to any payment obligations we may have under future arrangements with third parties, may have a substantial impact on our business, financial condition and profitability. Based on our recurring losses from operations incurred since inception, the

expectation of continuing operating losses for the foreseeable future, our outstanding and future payment obligations, and the potential need to raise additional capital to finance our future operations, we have concluded that substantial doubt exists about our ability to continue as a going concern for a period at least twelve months from the date of issuance of these unaudited consolidated financial statements.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Further, even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects and cause investors to lose all or part of their investments.

Risks Related to Our Product Candidates

Our business is highly dependent on the success of prula-cel. If we are unable to obtain regulatory approval for prula-cel in one or more indications and effectively commercialize this product candidate for the treatment of patients in indications for which we receive approval (if any), our business would be significantly harmed.

Our business and future success depends on our ability to obtain regulatory approval of, and then successfully commercialize prula-cel, our most advanced product candidate. In November 2024, we dosed our first LN patient in our Phase 1 clinical study of prula-cel in autoimmune diseases and subsequently expanded enrollment to include patients with SLE, SSc, IIM, SPS and AAV. On September 28, 2026, we announced updated clinical data from our prula-cel Phase 1 study in patients with LN and SLE. We are also advancing a Phase 1 study of prula-cel in patients with treatment-refractory rheumatoid arthritis (RA).

Our preclinical results or clinical results to date may not predict results for our planned or ongoing trials or any future studies of prula-cel, ADI-212, or any other product candidates. Because of the lack of evaluation of allogeneic products and gamma delta T cell therapy products in the clinic to date, any such product's failure, or the failure of other allogeneic T cell therapies or gamma delta T cell therapies, may significantly influence physicians' and regulators' opinions in regards to the viability of our entire pipeline of allogeneic T cell therapies, which could have a material adverse effect on our reputation. If our gamma delta T cell therapy is viewed as less safe or effective than autologous therapies or other allogeneic T cell therapies, our ability to develop other allogeneic gamma delta T cell therapies may be significantly harmed.

All of our product candidates, including prula-cel and ADI-212, will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. In addition, because prula-cel is our most advanced product candidate, and because our other product candidates are based on similar technology, if prula-cel encounters safety or efficacy problems, manufacturing problems, developmental delays, regulatory issues or other problems, our development plans and business would be significantly harmed, which could have a material adverse effect on our business, reputation and prospects.

Our gamma delta T cell candidates represent a novel approach to the treatment of autoimmune diseases and cancer indications that create significant challenges for us.

We are developing a pipeline of gamma delta T cell product candidates and a novel antibody platform that are intended for use in patients with certain autoimmune diseases and cancers. Advancing these novel product candidates creates significant challenges for us, including:

- negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- delays in enrolling or inability to enroll subjects in our clinical trials;
- manufacturing our product candidates to our specifications and in a timely manner to support our current and future clinical trials, and, if approved, commercialization;

- sourcing current and future clinical and, if approved, commercial supplies for the raw materials used to manufacture our product candidates;
- understanding and addressing variability in the quality of a donor's T cells, which could ultimately affect our ability to produce product in a reliable and consistent manner;
- inability to achieve efficacy in autoimmune disease and cancer patients following treatment with our product candidates;
- achieving a side effect profile from our product candidates in autoimmune diseases and cancer indications that makes them clinically and commercially attractive for further development;
- educating medical personnel regarding the potential side effect profile of our product candidates, if approved;
- using medicines to manage adverse side effects of our product candidates which may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment;
- conditioning patients with chemotherapy or other lymphodepletion agents in advance of administering our product candidates, which may increase the risk of adverse side effects;
- obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with development of allogeneic T cell therapies for autoimmune diseases and cancer; and
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy.

The success of our business, including our ability to obtain financing and generate any revenue in the future, will primarily depend on the positive efficacy and safety profile and durability of our product candidates in our clinical trials, regulatory approval, successful development and commercialization of our novel product candidates, and our ability to build out our manufacturing capabilities, any of which may never occur. We have not yet succeeded and may not succeed in demonstrating efficacy and safety or durability for any of our product candidates in clinical trials or in obtaining marketing approval thereafter. Given our early stage of development, it may be several years, if at all, before we have demonstrated the safety and efficacy of a product candidate sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business, which could have a material adverse effect on our results of operations and prospects.

Our product candidates are based on novel technologies, which makes it difficult to predict the likely success of such product candidates and the time and cost of product candidate development and obtaining regulatory approval.

We have concentrated our development efforts on our allogeneic gamma delta T cell therapy and our near-term success depends on the successful development of this therapeutic approach. We are in the early stages of developing our platform and product candidates and there can be no assurance that any development problems we have experienced or may experience in the future will not cause significant delays or result in unforeseen issues or unanticipated costs, or that any such development problems or issues can be overcome. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our future clinical studies or commercializing our products on a timely or profitable basis, if at all. In addition, our expectations with regard to the advantages of an allogeneic gamma delta T cell therapy platform relative to other therapies may not materialize or materialize to the degree we anticipate. Further, our scalability and costs of manufacturing may vary significantly as we develop our product candidates and understand these critical factors.

In addition, the clinical study requirements of the FDA, the European Medicines Agency (EMA) and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Allogeneic gamma delta T cell therapies are novel therapies, with no T cell therapies licensed to date in the United States or the European Union to treat autoimmune diseases. Approvals by the EMA and FDA for existing autologous CAR T cell therapies, such as Kymriah® and Yescarta®, as well as other pathways to approval, may not be indicative of what these regulators may require for approval of our therapies. Also, while we expect reduced variability in our product candidates compared to autologous products, we do not have significant clinical data supporting any benefit of lower variability. More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agencies may require for approval or what such regulatory agencies may require for approval in connection with new product candidates.

Our product candidates may also not perform successfully in clinical trials or may be associated with adverse events that distinguish them from the autologous CAR T-cell therapies that have previously been approved or alpha beta T cell therapies

that may be approved in the future. Unexpected clinical outcomes could materially and adversely affect our business, results of operations and prospects.

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

Undesirable or unacceptable side effects caused by our product candidates could cause us 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, the EMA or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Approved autologous CAR T-cell therapies and those under development have shown frequent rates of cytokine release syndrome and neurotoxicity, and adverse events have resulted in the death of patients. In January 2024, the FDA determined that new boxed warning language related to T-cell malignancies should be included in the labeling for all BCMA- and CD19-directed genetically modified autologous T cell immunotherapies. While we believe our gamma delta T cell approach may lessen such results, similar or other adverse events for our allogeneic gamma delta T cell product candidates may occur and could result in increased government regulation, unfavorable public perception and publicity, potential impacts on enrollment in our clinical trials, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates. In addition, while we anticipate our focus on gamma delta T cells may lessen the likelihood of graft versus host disease relative to therapies relying on unrelated alpha beta T cells, similar or other adverse events for our allogeneic gamma delta T cell product candidates may occur.

If unacceptable toxicities arise in the development of our product candidates (or third-party product candidates utilizing similar technologies), we could suspend or terminate our trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. A data safety monitoring board may also suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Novel therapeutic candidates, such as those we are developing, may result in novel side effect profiles that may not be appropriately recognized or managed by the treating medical staff. We anticipate having to train medical personnel using our product candidates to understand the side effect profile of our product candidates for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in serious adverse events including patient deaths. Based on available preclinical data and clinical experience with other cell therapy agents, the safety profile of our pipeline product candidates is expected to include cytokine release syndrome, neurotoxicity, and possibly additional adverse events. Any of these occurrences may have a material adverse effect our business, financial condition and prospects.

In addition to side effects and adverse events caused by any product candidates we may develop, the conditioning, administration process or related procedures that may be used with our product candidates may also cause adverse side effects. A T cell therapy patient is generally administered cytotoxic drugs to remove stem cells from the bone marrow to create sufficient space in the bone marrow for the modified stem cells to engraft and produce new cells. This procedure causes side effects and, among other potential risks, can transiently compromise the patient's immune system, known as neutropenia, and reduce blood clotting, known as thrombocytopenia. If we are unable to demonstrate that such adverse events were caused by the conditioning regimens used, administration process or related procedure, or were otherwise unrelated to the therapy candidate being studied, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates we may develop for any or all target indications. Even if we are able to demonstrate that adverse events are not related to our product candidate, such occurrences could affect patient recruitment, the ability of enrolled patients to complete the clinical trial or the commercial viability of any product candidates that obtain regulatory approval.

If we are required by the FDA to obtain approval of a companion diagnostic in connection with approval of any of our product candidates and we do not obtain, or face delays in obtaining, FDA approval of such companion diagnostic, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

If the FDA believes that the safe and effective use of any of our product candidates depends on an in vitro diagnostic, then it may require approval or clearance of that diagnostic as a companion diagnostic at the same time that the FDA approves our product candidates, if at all. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Depending on the data from our clinical trials, we may decide to collaborate with diagnostic companies during our clinical trial enrollment process to help identify patients with characteristics that we believe will be most likely to respond to our product candidates. If a satisfactory companion diagnostic is not commercially available in this situation, we may be required to develop or obtain such test, which would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities. In January 2024, FDA announced its intention to initiate the reclassification process for most in vitro diagnostics, including companion diagnostics. Further, FDA indicated that in addition to the reclassification process, FDA will continue taking a risk-based approach in the initial classification of individual in vitro diagnostics to determine whether a new test may be classified into class II through the de novo classification process. In so doing, FDA indicated that it may regulate most future companion diagnostics as class II devices. The approval or clearance of a companion diagnostic as part of the therapeutic product's further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect.

If the FDA or a comparable foreign regulatory authority requires approval or clearance of a companion diagnostic for any of our product candidates, whether before or after the product candidate obtains regulatory approval, we and/or third-party collaborators may encounter difficulties in developing and obtaining approval or clearance for these companion diagnostics. Any delay or failure by us or third party collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of the relevant product. We or our collaborators may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, any of which may prevent us from completing our clinical trials or, if approved, commercializing our product candidates on a timely or profitable basis, if at all.

Risks Related to Clinical Trials

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

Before obtaining regulatory approvals for the commercial sale 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. 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 may not be predictive of the results of later-stage clinical trials.

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. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved.

In addition, for the ongoing Phase 1 study of prula-cel and any future clinical trials that may be completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit marketing applications for our product candidates. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Any of the foregoing could have a material adverse effect on our business, prospects and financial condition.

We may not be able to file IND applications, or comparable regulatory submissions outside the United States, to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or analogous regulatory authorities may not permit us to proceed.

We have received clearance for INDs to evaluate prula-cel in clinical trials in a number of indications. Our pipeline also includes ADI-212, an optimized next-generation gene-edited and armored clinical candidate targeting prostate specific membrane antigen (PSMA). In August 2026, the FDA cleared our IND application for ADI-212 for the treatment of metastatic castration resistant prostate cancer (mCRPC), with Phase 1 enrollment anticipated to start in the fourth quarter of 2026. We aim to submit a new regulatory submission, such as an IND application or equivalent every 12-18 months. We may not be able to make these filings on the timelines we expect, which may cause delays in commencing additional clinical trials. Even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND application or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. Moreover, we cannot be sure that submission of an IND application for any of our other product candidates will result in the FDA allowing trials to begin, or that, once begun, issues will not arise that result in a decision by us, by independent institutional review boards (IRBs) or independent ethics committees, or by the FDA, the EMA or other regulatory authorities to suspend or terminate clinical trials. For example, we may experience manufacturing delays or other delays with IND-enabling studies or the FDA, the EMA or other regulatory authorities may require additional preclinical studies that we did not anticipate. The

inability to initiate clinical trials for any of our product candidates on the timeline we currently anticipate or at all could have a material adverse effect on our business, results of operations and prospects.

We may encounter substantial delays in our clinical trials, or may not be able to conduct our trials on the timelines we expect.

Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. Even if these trials begin as planned, issues may arise that could result in the suspension, or termination, or clinical hold of such clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and our ongoing or future clinical studies may not be successful. Factors that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical studies;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates;
- delays in reaching a consensus with regulatory agencies on study design;
- obtaining regulatory authorization to begin a trial, which may include the evaluation of a companion diagnostic, if applicable;
- delays in reaching an agreement on acceptable terms with prospective contract research organizations (CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required IRB approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly; or if FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting eligible patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs or other third parties to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's Good Clinical Practices (GCPs) requirements or applicable regulatory guidelines in other countries;
- challenges in transferring manufacturing processes to any new contract development and manufacturing organizations (CDMOs) or our manufacturing facilities or any other development or commercialization partner for the manufacture of product candidates;
- delays in having patients' complete participation in a study or failure to return for post-treatment follow-up;
- developing and implementing processes and procedures with collaborators, if applicable, relating to the collection and transfer of patient samples and the timely performance of a companion diagnostic on such samples;
- patients dropping out of a study;
- 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;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs;
- delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary raw materials;
- political conditions or conflicts in regions where we conduct or may seek to conduct our clinical trials; and
- manufacturing challenges, including delays in testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing.

Timelines for filing INDs for our product candidates are dependent on further preclinical and manufacturing success, which we work on with various third parties. We cannot be sure that we will be able to submit our INDs in a timely manner, if at all, or that submission of an IND application or IND amendment will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that result in the suspension, termination, or clinical hold of such clinical trials.

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 or formulation 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. Clinical study delays could also 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.

Monitoring safety of patients receiving our product candidates is challenging, which could adversely affect our ability to obtain regulatory approval and commercialize.

In our current and planned clinical trials of our product candidates, we have contracted with and expect to continue to contract with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these centers and hospitals may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. Any such difficulties could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending, terminating, or issuing a clinical hold on one or more of our clinical trials, and which could jeopardize regulatory approval. Medicines used at centers to help manage adverse side effects of prula-cel or our other product candidates may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment. Use of these medicines may increase with new physicians and centers administering our product candidates, any of which could have a material adverse effect on our ability to obtain regulatory approval and commercialize on the timelines anticipated or at all, which could have a material adverse effect on our business and results of operations.

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

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

- the patient eligibility criteria and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the number and location of clinical sites, including the potential impact of global or regional conflicts;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before the infusion of our product candidates or trial completion.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition may reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, some of our clinical trial sites are also being used by some of our competitors, which may reduce the number of patients who are available for our clinical trials in that clinical trial site.

Moreover, because our product candidates represent unproven methods for the treatment of autoimmune diseases and cancer, potential patients and their doctors may be inclined to use conventional therapies rather than enroll in our clinical trial. For cancer, they may use chemotherapy and hematopoietic cell transplantation or autologous CAR T cell therapies. Patients eligible for allogeneic CAR T cell therapies but ineligible for autologous CAR T cell therapies due to aggressive cancer and inability to wait for autologous CAR T cell therapies may be at greater risk for complications and death from therapy. For autoimmune diseases, potential patients may use therapies that focus on symptomatic relief.

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 trials and adversely affect our ability to advance the development of our product candidates.

Clinical trials are expensive, time-consuming and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our gamma delta T cell product candidates are based on novel technologies and will require the creation of inventory of mass-produced, "off-the-shelf" products, we expect that we will require extensive research and development and have substantial manufacturing and processing costs. In addition, costs to treat patients with autoimmune diseases and cancer and to treat potential side effects that may result from our product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher than for more conventional therapeutic technologies or drug products, which is expected to have a material adverse effect on our financial position and ability to achieve profitability.

As a result, because we have limited financial and managerial resources, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. For example, in January 2024, we announced we had deprioritized enrollment of large B cell lymphoma patients in our Phase 1 clinical trial of prula-cel in non-Hodgkin's lymphoma and in September 2024 we announced a strategic prioritization to focus prula-cel development resources on autoimmune indications. In July 2025, we also announced that we discontinued the development of ADI-270 for patients with metastatic/advanced clear renal cell carcinoma to prioritize corporate resources on prula-cel and ADI-212. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. Failure to allocate resources or capitalize on strategies in a successful manner will have an adverse impact on our business, financial condition and results of operations.

A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business.

We are currently conducting research and development activities outside of the United States, including in China, and plan to continue to globally develop our product candidates. Accordingly, we expect that our development programs will be subject to additional risks related to operating in foreign countries, including but not limited to:

- differing and changing regulatory requirements in foreign countries, including for clinical trial activities and product approvals;
- unexpected changes in tariffs (including tariffs that have been or may in the future be imposed by the United States or other countries), trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in the United States and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability and/or armed conflicts in particular foreign countries and markets;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;

- increasing geopolitical tensions between the U.S. and other countries in which we may operate and changes in a specific country's or region's political or economic environment especially with respect to a particular country's treatment of or stance towards other countries;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act (FCPA) or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

Furthermore, conducting clinical trials in countries outside the United States presents additional risks, including political and economic risks, such as armed conflict and economic embargoes or boycotts. We currently conduct and plan in the future to initiate clinical trials of prula-cel at sites outside of the United States, which may be located in countries involved in or impacted by political unrest and conflicts. For example, while we currently do not expect armed conflicts, such as the conflicts between the United States, Israel and Iran, Russia and Ukraine, or Israel and Hamas, or related developments to have a significant impact on our ability to obtain results from our clinical trials, further escalation (whether in these countries or surrounding areas) may adversely affect our ability to adequately conduct certain clinical trials and maintain compliance with relevant protocols due to, among other reasons, the prioritization of hospital resources away from clinical trials, reallocation or evacuation of site staff and subjects, or as a result of government-imposed curfews, warfare, violence, or other governmental action or other events that restrict movement. These developments may also result in our inability to access sites for monitoring or to obtain data from affected sites or patients going forward. We could also experience disruptions in our supply chain or limits to our ability to provide sufficient investigational materials in such countries and surrounding regions. Clinical trial sites may suspend or terminate the trials being conducted and patients could be forced to evacuate or choose to relocate, making them unavailable for initial or further participation in such trials. Alternative sites in these areas may not be available and we may need to find other countries to conduct the relevant trials. Furthermore, military action may prevent the FDA or other regulatory agencies from inspecting clinical sites in these countries. Such interruptions may delay our plans for clinical development and approvals for our product candidates.

We have conducted, and may in the future conduct, certain clinical trials for our product candidates outside of the U.S. However, the FDA and comparable foreign regulatory authorities may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We are conducting our Phase 1 clinical trial for prula-cel in treatment-refractory RA outside the U.S., and may conduct one or more of our subsequent clinical trials for our product candidates outside the U.S. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of this data is subject to certain conditions imposed by the FDA. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U.S., the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. For studies that are conducted only at sites outside of the U.S. and not subject to an IND, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, and require us to conduct additional clinical trials. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. If the FDA does not accept data from our clinical trials of our product candidates, we would likely need to conduct additional clinical trials, which would be costly and time consuming and could delay or halt our development of our product candidates.

These and other risks associated with our potential international operations may materially adversely affect our ability to develop our product candidates and attain or maintain profitable operations, which could have a material adverse effect on our business and results of operations.

Risks Related to Marketing Our Product Candidates

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

The FDA often approves new therapies initially only for use in patients who are currently not adequately treated with currently approved therapies. We expect to initially seek approval of prula-cel and our other product candidates in this setting. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of treatment and potentially as a first line therapy. There is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials, including potentially comparative trials against approved therapies. We are also targeting a similar patient population as autologous CAR T-cell product candidates, including approved autologous CAR T-cell products. Our therapies may not be as safe and effective as autologous CAR T-cell therapies and may only be approved for patients who are ineligible for autologous CAR T-cell therapy.

Our projections of both the number of people who have the indications we are targeting, as well as the subset of people with these indications in a position to receive second or later lines of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, patient foundations or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these indications. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

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

One of our core strategies is to pursue clinical development of additional product candidates beyond prula-cel. Our pipeline also includes ADI-212, an optimized next-generation gene-edited and armored product candidate targeting PSMA that we plan to submit a regulatory filing for the treatment of mCRPC. In August 2026, the FDA cleared our IND application for ADI-212. We plan to submit one new IND to the FDA every 12-18 months. Developing, obtaining regulatory approval for and commercializing additional gamma delta T cell product candidates will require substantial additional funding and is prone to the risks of failure inherent in medical product development. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we receive FDA approval to market our product candidates for the treatment of our targeted indications, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited. Moreover, a failure in obtaining regulatory approval of additional product candidates may have a negative effect on the approval process of any other, or result in losing approval of any approved, product candidate which could have a material adverse effect on our business and prospects.

We currently have no marketing and sales organization and as a company have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and as a company have no experience in marketing products. We may develop a marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements with third parties regarding the sales and marketing of our products; however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that it will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product that receives regulatory approval in the United States or overseas. If we are unable to successfully market and distribute our products, either on our own or in collaboration with third parties, our business, results of operations and prospects could be materially adversely affected.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds, drugs, or biological products that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

Specifically, engineered T cells face significant competition in both the CAR and T cell receptor (TCR) technology space from multiple companies. Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is affected by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

Risks Related to Manufacturing

Although we have commenced manufacturing operations at our manufacturing facility, we currently depend on the ability of our third-party suppliers and manufacturers with whom we contract to perform adequately, particularly with respect to the timely production and delivery of our product candidates, including prula-cel. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

Although we commenced manufacturing operations at our Redwood City facility, we rely and expect to continue to rely to a significant extent on third parties for the manufacture of our product candidates for preclinical and clinical development. We may not be able to achieve clinical or commercial manufacturing and cell processing on our own or through our CDMOs, including timely supply of "off-the-shelf" product to satisfy demands to support clinical trials of any of our product candidates. To the extent we are not able to obtain timely supply of "off-the-shelf" product, the anticipated timing for our clinical trials and the development of our product candidates could be adversely impacted. Very few companies have experience in manufacturing gamma delta T cell therapy derived from blood of unrelated donors, and gamma delta T cells require several complex manufacturing steps before being available as a mass-produced, "off-the-shelf" product. We have limited experience in managing the allogeneic gamma delta T cell engineering process, and our allogeneic processes may be more difficult or more expensive than the approaches taken by our competitors. We cannot be sure that the manufacturing processes employed by or on our behalf will result in T cells that will be safe and effective.

Our operations remain subject to review and oversight by the FDA and the FDA could object to our use of any manufacturing facilities. Even if our product candidates are approved, we would be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with current Good Manufacturing Practices (cGMPs) and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review.

Our cost of goods development is at an early stage. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates.

The manufacture of biopharmaceutical products is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. The occurrence of any of such problems could adversely impact the availability of products for our clinical trials and commercial sale. Furthermore, if contaminants are discovered in our supply of product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We have experienced manufacturing delays due to these issues in the past and cannot assure you that any stability or other issues relating to the manufacture of our product candidates will not occur in the future.

Our product candidates and any products that we may develop may compete with other companies' product candidates and approved products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

We may fail to manage the logistics of storing and shipping our product candidates. Storage failures and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could result in loss of usable product or prevent or delay the delivery of product candidates to patients.

We may also experience both internal and external manufacturing difficulties due to resource constraints or as a result of labor disputes. We have experienced external manufacturing difficulties in the past; if we were to continue to encounter any of these difficulties, our ability to provide our product candidates to patients would be jeopardized, which could have a material adverse effect on our business, results of operations and prospects.

Risks Related to Our Operations

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. Although we announced a workforce reduction in July 2025, we expect that we will have a need to recruit and hire qualified personnel as we advance our programs and expand operations. Our recent workforce reduction could impede future recruiting and hiring efforts. Failure to successfully recruit and retain personnel could impact our anticipated development plans and timelines.

We conduct substantially all of our operations at our facilities in the San Francisco Bay Area. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in this market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options and restricted stock units that vest over time. The value to employees of stock options that vest over time may be significantly affected by fluctuations in our stock price that are beyond our control. Declines in our stock price generally reduce the value of equity awards granted to its employees. To the extent our stock price declines, our ability to incentivize, retain or attract qualified talent could be negatively impacted. Such declines in stock price may result in additional "underwater" stock options held by certain employees and officers. For example, in August 2024, certain of our executive officers entered into an option cancellation agreement to surrender certain underwater stock options.

The value of our stock options may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. To provide added incentives to retain and motivate key contributors, our board of directors approved a stock option repricing in August 2023. Despite this, we may have difficulty retaining key personnel, which could adversely affect our business and further development of our product candidates.

We will need substantial additional financing to develop our product candidates and implement our operating plans. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates.

We expect to spend a substantial amount of capital for the clinical development of our product candidates, including the ongoing and future clinical trials for prula-cel and preparations for a regulatory filing for ADI-212. We will need substantial additional financing to develop our products and implement our operating plans. In particular, we will require substantial additional financing to enable commercial production of our products and initiate and complete registration trials for multiple products. Further, if approved, we will require significant additional amounts in order to launch and commercialize our product candidates.

As of the date of this Quarterly Report on Form 10-Q, we believe that with $100.9 million in cash, cash equivalents and short-term investments in treasury securities as of September 30, 2026, we are capitalized into the second half of 2027. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require additional capital for the further development and commercialization of our product candidates, including funding our internal manufacturing capabilities and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate.

We cannot be certain that additional funding will be available on acceptable terms, 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 have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. In addition, certain of our license and collaboration agreements require us to make cash payments upon the achievement of certain milestone events. In the event we are unable to meet the payment obligations under these agreements, the agreements may be terminated in accordance with the terms of such agreements. Further, we could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Additionally, United States and global economic uncertainty, higher interest rates and diminished credit availability may limit our ability to incur indebtedness on favorable terms. Furthermore, the impact of geopolitical tension, such as a deterioration in the bilateral relationship between the United States and China, an escalation in conflict between Russia and Ukraine, the ongoing armed conflict between the United States, Israel and Iran, or the ongoing armed conflict in Israel and the Gaza strip, including any resulting sanctions, export controls or other restrictive actions, also could lead to disruption, instability and volatility in the global markets, which may have an impact on our ability to obtain additional funding.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.

As of the date of this Quarterly Report on Form 10-Q, we believe that with $100.9 million in cash, cash equivalents and short-term investments in treasury securities as of September 30, 2026, we are capitalized into the second half of 2027. Our ability to continue as a going concern beyond this point will require us to obtain additional funding. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, limit, reduce or terminate our product development or future commercialization efforts of one or more of our product candidates, or may be forced to reduce or terminate our operations. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. In our future required quarterly assessments, we may again conclude that substantial doubt exists about our ability to continue as a going concern, and future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there exists substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, if at all.

We have grown rapidly and will need to continue to grow the size of our organization, and it may experience difficulties in managing this growth.

As our development and commercialization plans and strategies develop, and as we have transitioned into operating as a public company, we have rapidly expanded our employee base. Current and future growth imposes 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 our growth, and our management may also have to divert a disproportionate amount of our attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants, pursuant to arrangements which expire after a certain period of time, to provide certain services, including certain research and development as well as general and administrative support. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain 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, or 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, which could have a material adverse effect on our business, results of operations and prospects.

We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. For instance, our License and Collaboration Agreement (the Regeneron Agreement) with Regeneron Pharmaceuticals, Inc. (Regeneron) requires significant research and development commitments that may not result in the development and commercialization of product candidates. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction, which could have a material adverse effect on our business and results of operations.

Our cash preservation activities, including the workforce reduction plan, may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In July 2025, we implemented our workforce reduction plan. In connection with the workforce reduction plan, we incurred costs of approximately $2.3 million, which were primarily one-time severance benefits. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our workforce reduction plan may be disruptive to our operations. For example, headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of remaining employees.

We may become subject to litigation or threatened litigation or other claims that may divert management's time and attention, require us to pay damages and expenses or restrict the operation of our business.

We may become subject to disputes with commercial parties with whom we maintain relationships or other parties with whom we do business. Any such dispute could result in litigation between us and the other parties. Whether or not any dispute actually proceeds to litigation, we may be required to devote significant management time and attention to its successful resolution (through litigation, settlement or otherwise), which would detract from our management's ability to focus on our business. Any such resolution could involve the payment of damages or expenses by us, which may be significant. In addition, any such resolution could involve our agreement with terms that restrict the operation of our business.

Risks Related to Doing Business in China and Our International Operations

The pharmaceutical industry in China is highly regulated and such regulations, including the Foreign Investment Law and the "negative list," are subject to change which may affect development approval and commercialization of our product candidates.

The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the development, approval, registration, manufacturing, packaging, licensing and marketing of new drugs. For example, under the People's Republic of China (PRC) law, before we or our subsidiaries commence a clinical trial with Shanghai Adicet Biotechnology Co., Ltd., (Shanghai Adicet), an approval or filing, as the case may be, needs to be obtained in advance for any projects in respect of human genetic resources in order to collect any biological samples that contain the genetic material of Chinese human subjects. Any failure to obtain such approval or filing could cause such projects to be suspended by governing authorities, and may result in fines. Investigator-initiated trials cannot be implemented in a medical and healthcare institution without first being approved by such medical and healthcare institutions. Such medical and healthcare institutions shall file such approval to the medical and healthcare authority which issues its operating license for record. Furthermore, under relevant PRC laws, a license for use of laboratory animals is required for performing experimentation on animals. Any failure to fully comply with such requirements may result in the invalidation of our experimental data. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our product candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. PRC authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach are aligned with the PRC government's regulatory policies, but we cannot ensure that our strategy and approach will continue to be aligned.

In addition, the Foreign Investment Law in China grants foreign invested entities the same treatment as PRC domestic entities, except for those foreign invested entities that operate in industries deemed to be either "restricted" or "prohibited" in the "negative list" published by the Ministry of Commerce, and the National Development and Reform Commission (2024 Negative List). We and our PRC subsidiaries, Adicet (Shanghai) Biotechnology Co., Ltd. (Adicet Shanghai), and Shanghai Adicet, each a wholly foreign-owned enterprise (WFOE), are currently considered to be a foreign invested entity in China.

The 2024 Negative List provides that foreign investment is prohibited in the development and application of human stem cell or gene diagnostic and therapeutic technologies. To date, there has been no official interpretation of the scope of "human stem cell or gene diagnostic and therapeutic technologies" and the application of this regulation remains unclear. If discovering and developing our allogeneic gamma delta T cell therapies are deemed by relevant PRC regulatory agencies as falling into the category of "human stem cell or gene diagnostic and therapeutic technologies," Adicet Shanghai and Shanghai Adicet would be prohibited from engaging in the research or development of such technologies. It is also noted that in September 2024, Ministry of Commerce, National Healthcare Commission and National Medical Products Administration of PRC jointly announce a pilot policy (2024 Pilot Policy) to allow foreign invested entities in Free Trade Zone of Beijing, Shanghai, Guangdong and Hainan to develop human stem cell or gene diagnostic and therapeutic technologies, pursuant to which Shanghai Adicet, whose registered address is within the territory of Free Trade Zone of Shanghai, conduct our research and development activities in PRC.

Any of the above factors may affect the development, approval and commercialization of our product candidates, which could have a material adverse effect on our business and financial condition.

The uncertainties in the PRC legal system regarding the Foreign Investment Law may subject our contractual arrangements to different interpretations or enforcement challenges, or subject us to severe penalties or force us to relinquish our interests in our operations.

In May 2024, we formed Adicet Shanghai, located in Shanghai, PRC, as a wholly owned subsidiary of Adicet Therapeutics. Through Adicet Shanghai, we operate our business in PRC pursuant to a series of contractual arrangements between Adicet Shanghai and Shanghai Adicet, and the Shanghai Adicet's shareholders, which enable us to (i) direct the activities of Shanghai Adicet that most significantly impact Shanghai Adicet's economic performance, (ii) receive substantially all of the economic benefits of Shanghai Adicet and its subsidiary, and (iii) have an exclusive option to purchase all or part of the equity interests and assets in Shanghai Adicet, when and to the extent permitted by PRC laws. As a result of these contractual arrangements, Adicet Therapeutics is considered the primary beneficiary of Shanghai Adicet and Shanghai Adicet's subsidiaries (if any) for accounting purposes and is able to consolidate the financial results of Shanghai Adicet in the consolidated financial statements in accordance with accounting principles generally accepted in the United States of America. Investors in our common stock do not hold any ownership interest, directly or indirectly, in Shanghai Adicet in China, and we merely have a contractual relationship with the operating entity in China.

Our PRC legal counsel based on its understanding of the relevant laws and regulations, is of the opinion that (i) the ownership structure of Adicet Shanghai and Shanghai Adicet are in compliance with applicable PRC laws or regulations and (ii) such contractual arrangements constitute valid, legal and binding obligations enforceable against each party of such agreements in accordance with the terms of each agreement, and will not result in any violation of PRC laws or regulations currently in effect. However, our PRC legal counsel has also advised us that there are substantial uncertainties regarding the interpretation and application of current and future PRC laws, regulations and rules. Accordingly, the PRC regulatory authorities may take a view that is contrary to the opinion of our PRC legal counsel.

Following the 2024 Pilot Policy which allows foreign invested entities in Free Trade Zone of Beijing, Shanghai, Guangdong and Hainan to develop human stem cell or gene diagnostic and therapeutic technologies, Adicet Therapeutics entered into an equity transfer agreement with the then-stockholders of Shanghai Adicet to acquire 100% equity interests of Shanghai Adicet from its then-stockholders (the Acquisition). In connection with the Acquisition, tax filings and registration with the Administration for Market Regulation of Shanghai Adicet were completed in August 2025. Upon completion of the registration, Shanghai Adicet is now a wholly owned subsidiary of Adicet Therapeutics and will continue to conduct research and development activities in China, and the contractual arrangements between Adicet Shanghai and Shanghai Adicet is terminated accordingly.

Changes in U.S. and Chinese regulations may impact our business, financial condition, and our operating results.

The U.S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations, and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with certain operations based in China. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the United States or to China, our industry or on us. We conduct research activities and have business operations both in the United States and China. Any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with certain operations based in China, capital controls or tariffs, may affect the competitive position of our product candidates, the hiring of scientists and other research and development personnel, the demand for our product candidates, the import or export of raw materials in relation to drug development, our ability to raise capital, or prevent us from selling our product candidates in certain countries. Furthermore, the SEC has issued statements primarily focused on companies with certain operations based in China, such as us. For example, in 2021, the Chairman of the SEC, issued a Statement on Investor Protection Related to Recent Developments in China, pursuant to which he stated that he has asked the SEC staff to engage in targeted additional reviews of filings for companies with certain operations based in China. The statement also addressed risks inherent in companies with variable interest entity structures.

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated or if the U.S. or Chinese governments take retaliatory actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition and results of operations.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the PRC State Council promulgated the Measures for the Management of Scientific Data (the Scientific Data Measures), which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, researchers conducting research funded, at least in part, by the PRC government may be required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Currently, as the term "state secret" is not clearly defined, there is no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad, or to our foreign partners in China.

If we are unable to obtain the necessary approvals in a timely manner, or at all, our research and development of product candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions and prospects. If relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to specific administrative penalties imposed by those government authorities.

Compliance with China's Data Security Law, Cyber Security Law, Personal Information Protection Law, regulations and guidelines relating to the multi-level protection scheme on cyber security and any other future laws and regulations may entail significant expenses and could affect our business.

China has implemented an extensive legal framework governing data security, protection and privacy. China's Data Security Law took effect in September 2021 and provided that the data processing activities must be conducted based on "data classification and hierarchical protection system" for the purpose of data protection and prohibits entities in China from transferring data stored in China to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government.

Additionally, China's Cyber Security Law, promulgated by the Standing Committee of the National People's Congress, which came into effect in 2017, and the Administrative Measures for the Hierarchical Protection of Information Security promulgated by the Ministry of Public Security, National Administration of State Secrets Protection, State Cryptography Administration and other government authority in 2007, requires companies to take certain organizational, technical and administrative measures and other necessary measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that China adopts a multi-level protection scheme (MLPS), under which network operators are required to perform obligations of security protection to ensure that the network is free from interference, disruption or unauthorized access, and prevent network data from being disclosed, stolen or tampered. Under the MLPS, entities operating information systems must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level of the entity's information and network systems. These levels range from the lowest Level 1 to the highest Level 5 pursuant to a series of national standards on the grading and implementation of the classified protection of cyber security. The grading result will determine the set of security protection obligations that entities must comply with. Entities classified as Level 2 or above should report the grade to the relevant government authority for examination and approval.

Also, the Standing Committee of the National People's Congress released the Personal Information Protection Law, which became effective in 2021. The Personal Information Protection Law provided a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The Personal Information Protection Law also provides that critical information infrastructure operators and personal information processing entities who process personal information meeting a volume threshold set by Chinese cyberspace regulators are also required to store in China personal information generated or collected in China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the Personal Information Protection Law contains proposals for significant fines for serious violations of up to Renminbi 50 million or 5% of annual revenues from the prior year and may also be ordered to suspend any related activity by competent authorities. Meanwhile, the State Council of the PRC promulgates the Regulations on the Administration of Network Data Security, which came into effect on January 1, 2025, and put forward a series of detailed requirements regarding data protection. With regard to the cross-border transfer of personal information, the Cyberspace Administration of China (CAC) released the Regulations on Promoting and Regulating Cross-border Data Flows in 2024. The Regulations on Promoting and Regulating Cross-border Data Flows establishes the latest regulatory framework for the cross-border transfer of personal information. The personal information handler should pass the security assessment, submit the standard contract signed for the provision of personal information abroad, or be certified by a specialized agency for the protection of personal information authentication before the cross-border transfer of the personal information when certain threshold provided in the Regulations on Promoting and Regulating Cross-border Data Flows is reached. Over the past year, the CAC has issued regulatory measures focused on data security and cross-border data flows, including the February 14, 2025, "Administrative Measures for Personal Information Protection Compliance Audits", June 27, 2025, "Guidelines for the Declaration of Data Outbound Security Assessment (3rd Edition)", and September 11, 2025, "Measures for the Administration of National Cybersecurity Incident Reporting". In addition, the National Information Security Standardisation Technical Committee (TC260) issued its finalized "Cybersecurity Standard Practice Guidelines: Personal Information Protection Compliance Audit Requirements". The CAC has also increased its enforcement activity, including a regulatory sweep focused on app and SDK developers. We expect the CAC and additional Chinese regulators to maintain a high level of scrutiny in the data security, cross-border data transfer and artificial intelligence space.

In addition, certain industry-specific laws and regulations affect the collection and transfer of data in the PRC. The Regulations on the Administration of Human Genetic Resources of the PRC (the HGR Regulation), promulgated by the State Council, came into effect in 2019 and was thereafter revised in 2024. It stipulates that foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals are forbidden to collect, preserve and

export China's human genetic resources. Foreign organizations and the entities established or actually controlled by foreign organizations or individuals may only utilize and be provided with China's human genetic resources after satisfaction of all requirements under the HGR Regulation and other applicable laws, such as (i) China's human genetic resources being utilized only in international cooperation with Chinese scientific research institutions, universities, medical institutions, and enterprises for scientific research and clinical trials after completion of requisite approval or filing formalities with competent governmental authorities, and (ii) China's human genetic resources information being provided after required filing and information backup procedures have been gone through. In 2020, the Standing Committee of the National People's Congress promulgated the Biosecurity Law of the PRC, which was later amended in 2024, and it reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative sanctions where China's human genetic resources are collected, preserved, exported or used in international cooperation in violation of applicable laws. The Ministry of Science and Technology published the Implementing Rules for the Regulations on the Administration of Human Genetic Resources (the HGR Implementing Rules), which came into effect in 2023. The HGR Implementing Rules have, among other things, further clarified the scope of China's human genetic resources information, improved the procedure rules for applicable approval, filing and security review, and refined the provisions with respect to the forbiddance on the collection, preservation and export of China's human genetic resources by foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals. There remain significant uncertainties as to how various provisions of the HGR Regulation and the related laws and regulations may be interpreted and implemented. Given such uncertainty, although we have made great efforts to comply with mandatory requirements of laws and government authorities in this regard, we cannot assure you that we will be deemed at all times in full compliance with the HGR Regulation, the Biosecurity Law of the PRC, the HGR Implementing Rules and other applicable laws in our utilizing of and dealing with China's human genetic resources. As a result, we may be exposed to compliance risks under the HGR Regulation, the Biosecurity Law of the PRC and the HGR Implementing Rules.

Interpretation, application and enforcement of these laws, rules and regulations evolve from time to time and their scope may continually change, through new legislation, amendments to existing legislation or changes in enforcement. Compliance with China's new Cyber Security Law and Data Security Law could significantly increase the cost to us of providing our service offerings, require significant changes to our operations or even prevent us from providing certain service offerings in jurisdictions in which we currently operate or in which we may operate in the future. Despite our efforts to comply with applicable laws, regulations and other obligations relating to privacy, data protection and information security, it is possible that our practices, offerings or platform could fail to meet all of the requirements imposed on us by the Cyber Security Law, the Data Security Law and/or related implementing regulations. Any failure on our part to comply with such law or regulations or any other obligations relating to privacy, data protection or information security, or any compromise of security that results in unauthorized access, use or release of personally identifiable information or other data, or the perception or allegation that any of the foregoing types of failure or compromise has occurred, could damage our reputation, discourage new and existing counterparties from contracting with us or result in investigations, fines, suspension or other penalties by Chinese government authorities and private claims or litigation, any of which could adversely affect our business, financial condition and results of operations. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition and results of operations. Moreover, the legal uncertainty created by the Data Security Law, the recent Chinese government actions could adversely affect our ability, on favorable terms, to raise capital, including engaging in follow-on offerings of our securities in the U.S. market.

Pharmaceutical companies operating in China are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our current and planned operations in China.

The pharmaceutical industry in China is subject to extensive government regulation and supervision. The regulatory framework addresses all aspects of operating in the pharmaceutical industry, including product development activities, clinical trials, registration, production, distribution, packaging, labeling, storage and shipment, advertising, licensing and post-approval pharmacovigilance certification requirements and procedures, periodic renewal and reassessment processes, data security and data privacy protection requirements and compliance and environmental protection. Violation of applicable laws and regulations may materially and adversely affect our business by impacting Shanghai Adicet through which we conduct certain research and development activities. The regulatory framework governing the pharmaceutical industry in China is subject to change and amendment from time to time. Any such change or amendment could materially and adversely impact our business, financial condition and prospects. The Chinese government has introduced various reforms to the Chinese healthcare system in recent years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services. The specific regulatory changes under the various reform initiatives remain uncertain. The implementing measures to be issued may not be sufficiently effective to achieve the stated goals, and as a result, we may not be able to benefit from such reform to the extent we expect, if at all. Moreover, the various reform initiatives could give rise to regulatory developments, such as more burdensome administrative procedures, which may have an adverse effect on our business and prospects.

We may be exposed to liabilities under the FCPA, and similar anti-corruption and anti-bribery laws of China and other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions and import laws and

regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and any determination that we have violated these laws could have a material adverse effect on our business or our reputation.

Our operations are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of China and other countries in which we operate. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from, directly or indirectly, offering, authorizing or making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business or other advantage. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. As our business expands, the applicability of the FCPA and other anti-bribery laws to our operations will increase. If our procedures and controls to monitor anti-bribery compliance fail to protect us from reckless or criminal acts committed by our employees or agents or if we, or our employees, agents, contractors or other collaborators, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

Any failure to comply with Chinese regulations regarding the registration requirements for our employee equity incentive plans may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition and results of operations.

In 2012, the State Administration of Foreign Exchange (SAFE) promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (the Stock Option Rules). In accordance with the Stock Option Rules and other relevant rules and regulations, Chinese citizens or non-Chinese citizens residing in China for a continuous period of not less than one year who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a Chinese subsidiary of such overseas listed company, and complete certain procedures. Our employees who are Chinese citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plans are subject to such regulation. We plan to assist our employees to register their equity awards. However, any failure of our Chinese individual beneficial owners and holders of equity awards to comply with the SAFE registration requirements may subject them to fines and legal sanctions and may limit the ability of our Chinese subsidiaries to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our employees under Chinese law.

Risks Related to Business Disruptions

Business disruptions, including armed conflicts, could substantially delay our clinical trials or seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CDMO, CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, armed conflicts, medical epidemics, such as public health crises or other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our ability to manufacture our product candidates could be disrupted if our operations or those of our suppliers are affected by a man-made or natural disaster, the severity and frequency of which may be amplified by global climate change, or other business interruptions. We have facilities located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Global conflicts may increase the likelihood of supply or clinical trial interruptions which could impact our ability to find the materials we need to make our product candidates or conduct our clinical trials.

Ongoing conflicts, including conflicts between Russia and Ukraine and Israel and Hamas and a deterioration in the bilateral relationship between the United States and PRC, may increase the likelihood of supply or clinical trial interruptions and hinder our ability to find the materials we need to make our product candidates or conduct our clinical trials. Supply disruptions make it more difficult for us to find favorable pricing and reliable sources for the materials we need, which increases pressure on our costs and increases the risk that we may be unable to acquire the necessary goods and services to successfully manufacture our product candidates. If we were to encounter difficulties related to global conflicts, our ability to provide our product candidates and to conduct our preclinical studies or clinical trials, such as our ongoing, planned, or future clinical trials of prula-cel, could be delayed or suspended. Any delay or interruption in the supply of trial materials or disruption to the clinical trial itself could delay the completion of such trials, increase the costs associated with maintaining these research and development activities and, depending upon the period of delay, require us to commence new preclinical studies or clinical trials at additional expense or terminate such trials completely.

Changes in the political and economic policies or in relations between China and the United States may affect our business, financial condition, and results of operations.

Due to our operations in China, our business, results of operations, financial condition and prospects may be influenced to a certain degree by economic, political, legal and social conditions in China or changes in government relations between China and the United States or other governments. The Chinese government may intervene in or influence our operations, which could result in a change in our operations. Any economic downturn, whether actual or perceived, further decrease in economic growth rates or an otherwise uncertain economic outlook could affect our business, financial condition and results of operations. In addition, the global macroeconomic environment is facing challenges. It is unclear whether these challenges and uncertainties will be contained or resolved, and what effects they may have on the global political and economic conditions, and our business operations in the long term. There is significant uncertainty about the future relationship between the United States and China with respect to trade policies, treaties, government regulations and tariffs. The Chinese government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall Chinese economy, but may have a negative effect on us. Due to our operations in China, any future Chinese, U.S. or other rules and regulations that place restrictions on capital raising or other activities by companies with operations in China could affect our business and results of operations. If the business environment in China deteriorates from the perspective of domestic or international investment, or if relations between China and the United States or other governments deteriorate and geopolitical tensions between China and the United States increase, our business in China and United States may also be affected.

Inadequate funding and/or staffing for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the approval of our product candidates rely, which would negatively impact our business.

Without appropriation of necessary funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, adequate staffing, furloughs, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, leadership and policy changes. Average review times at the agency have fluctuated in recent years as a result. For example, in 2025, changes and cuts in FDA staffing have been reported as resulting in delays in the FDA's responsiveness or in its ability to review IND submissions or marketing applications. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

For example, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, in some instances have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs or a widespread freeze on federal funding continues or occurs in the future, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business, including our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

In addition, following the change in the U.S. presidential administration in 2025, there is substantial uncertainty as to the extent and manner in which the U.S. government will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidates. Additionally, the administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates.

Also, state governments may seek to address or react to changes at the federal level with changes to their regulatory frameworks in a manner that could impact our operations.

Significant political, trade, regulatory developments, and other circumstances beyond our control, could have a material adverse effect on our financial condition or results of operations.

We operate globally and, if approved, we may sell our products in countries throughout the world. Significant political, trade, or regulatory developments in the jurisdictions in which we may sell our products, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, the implementation of tariffs by the U.S. government have led to increased trade and political tensions, between not only the U.S. and China, but also between the U.S. and other countries in the international community. In response to tariffs, other countries have implemented and may in the future implement additional retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our business, financial condition or results of operations.

Risks Related to Healthcare Regulation

Our relationships with customers, physicians including clinical investigators, CROs and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, transparency laws, government price reporting and other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners, vendors, or other agents violate these laws, we could face substantial penalties.

These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations 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, sales commission, customer incentive and other business arrangements. We may also be subject to federal, state and foreign laws governing the privacy and security of identifiable patient information. For further discussion on U.S. healthcare regulations, see the section entitled "*Business–Government Regulation and Product Approval—Other U.S. Healthcare Laws and Compliance Requirements*" in our Annual Report on Form 10-K for the year ended December 31, 2025.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, or our arrangements with physicians, could be subject to challenge under one or more of such laws. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and/or significant penalties.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct or business noncompliance, 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 be in compliance 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 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 themselves 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, debarment, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, 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 United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Data protection, privacy and similar laws restrict access, use, and disclosure of information, and failure to comply with or adapt to changes in these laws could materially and adversely harm our business.

We are subject to federal and state data privacy and security laws and regulations, and laws and expectations relating to privacy continue to evolve. Changes in these laws may limit our data access, use and disclosure, and may require increased expenditures. In addition, data protection, privacy and similar laws protect more than patient information and, although they vary by jurisdiction, these laws can extend to employee information, business contact information, provider information, and other information relating to identifiable individuals. For example, the California Consumer Privacy Act (CCPA) requires covered businesses to, among other things, provide notices to California consumers regarding the collection, use and disclosure of such consumers' personal information and afford such consumers new rights with respect to their personal information, including the right to opt out of certain sales of personal information. In addition, the California Privacy Rights Act (CPRA), which amended the CCPA, became effective on January 1, 2023 and imposed additional obligations on companies covered by the legislation. The CPRA modified the CCPA and has created a state agency that is vested with authority to implement and enforce the CCPA. There are also states that are specifically regulating health information or specific types of information, such as biometric information, and regulators and legislators are continuing to propose and adopt new laws and regulations protecting privacy and certain types of personal information. For example, Washington's My Health My Data Act (MHMDA) regulates the collection and sharing of consumer health information and includes a private right of action, which further increases compliance risks.

Given the breadth and depth of changes in privacy, data protection and consumer protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and ongoing review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that store, process or transfer personal data on our behalf. Compliance with such laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business. Any failure or perceived failure by us to comply with such laws and regulations could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations. There is also the threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

The collection and use of personal health data in the European Economic Area (EEA) is governed by the General Data Protection Regulation (EU GDPR) and the United Kingdom's General Data Protection Regulation (UK GDPR, together with the EU GDPR, GDPR). The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR enhances data protection obligations for controllers of personal data, including stringent requirements relating to ensuring an appropriate legal basis or condition applies to the processing of personal data, stricter requirements relating to obtaining consent from data subjects, stricter requirements around the collection of sensitive data (such as health data), expanded disclosures about how personal data is used, requirements to conduct data protection impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements, implementing safeguards to protect the security and confidentiality of personal data and creates direct obligations on service providers acting as processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the United States.

Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the GDPR. On June 19, 2025, the UK Government adopted the Data (Use and Access) Act 2025 (the DUAA). This may lead to additional compliance costs and could increase our overall risk. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and cost to our handling of EU personal information and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EU. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU GDPR, the European Commission issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted (UK Adequacy Decision). In December 2025, the European Commission adopted a decision to extend the validity of the UK adequacy decision for six years until December 2031, determining that the UK continues to offer a level of data protection that is "essentially equivalent" to the EU standards. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the United Kingdom to countries not regarded by the United Kingdom as providing adequate protection. The UK government has confirmed that personal data transfers from the United Kingdom to the EEA remain free flowing.

To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with European and UK data protection laws. The European Commission has issued forms of standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR). The UK is not subject to the EC's new standard contractual clauses but has published the UK International Data Transfer Agreement and International Data Transfer Addendum to the new standard contractual clauses (the IDTA), which enable transfers from the UK. For new transfers, the IDTA already needs to be in place, and must be in place for all existing transfers from the UK from March 21, 2024 Companies relying on standard contractual clauses to govern transfers of personal data to third countries (in particular the United States) will need to assess whether the data importer can ensure sufficient guarantees for safeguarding the personal data under GDPR. This assessment includes assessing whether third party vendors can also ensure these guarantees. The same assessment is required for transfers governed by the IDTA. Further, the EU and United States have adopted its adequacy decision for the EU-U.S. Data Privacy Framework (Framework), which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework has already been challenged and could be invalidated like its predecessor frameworks. We are required to implement these new safeguards when conducting restricted data transfers under the GDPR and doing so will require significant effort and cost.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to €20 million (or £17.5 million in the UK) or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR or UK GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR, will require significant time, resources and expense, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

In addition, many other jurisdictions outside of Europe are also considering and/or enacting new and/or amended comprehensive data protection legislation. We also continue to see jurisdictions imposing data localization laws. These regulations may interfere with our intended business activities, inhibit our ability to expand into those markets or prohibit us from continuing to offer services in those markets without significant additional costs. Because the interpretation and application of many privacy and data protection laws (including the GDPR), commercial frameworks, and standards are uncertain, it is possible that these laws, frameworks, and standards may be interpreted and applied in a manner that is inconsistent with our existing data management practices and policies. If so, in addition to the possibility of fines, lawsuits, breach of contract claims, and other claims and penalties, we could be required to fundamentally change our business activities and practices or modify our solutions, which could have an adverse effect on our business. Any inability to adequately address privacy and security concerns, even if unfounded, or comply with applicable privacy and security or data security laws, regulations, and policies, could result in additional cost and liability to us, damage our reputation, inhibit our ability to conduct trials, and adversely affect our business.

Data protection, privacy and similar laws protect more than patient information and, although they vary by jurisdiction, these laws can extend to employee information, business contact information, provider information, and other information relating to identifiable individuals. Failure to comply with these laws may result in, among other things, civil and criminal liability, negative publicity, damage to our reputation, and liability under contractual provisions. In addition, compliance with such laws may require increased costs to us or may dictate that we not offer certain types of services in the future.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act (AI Act) — the world's first comprehensive AI law – which has entered into force on August 1, 2024 and most provisions of which will become effective on August 2, 2026. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or use AI systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. Furthermore, in the U.S., a number of states have proposed and passed laws regulating various uses of AI, and federal regulators have issued guidance affecting the use of AI in regulated sectors.

We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security, including as informed by regulatory guidance. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Risks Related to Our Financial Position

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

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC stated all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. Although we are not a borrower or party to any such instruments with SVB, Signature or any other financial institution currently in receivership, if any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

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

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

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

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- loss of access to revolving existing credit facilities or other working capital sources and/or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;

- potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements;
- potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

We have in the past failed and may in the future fail to achieve and maintain effective internal control over financial reporting could harm our business and negatively impact the value of our common stock.

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

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended. We will remain a non-accelerated filer as long as we qualify to be a "smaller reporting company" under Rule 12b-2 of the Exchange Act, which will be for as long as either (i) the market value of our common stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700.0 million as of the prior June 30. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. To continue to achieve and maintain compliance with Section 404, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, from time to time we may not be able to conclude that our internal control over financial reporting is effective as required by Section 404.

We expect to continue our efforts to improve our control processes, though there can be no assurance that our efforts will ultimately be successful or avoid potential future material weaknesses, and we expect to continue incurring additional costs as a result of these efforts. If we are unable to successfully remediate any future material weaknesses in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

We have previously identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future. If we fail to remediate a material weakness or if we otherwise fail to establish and maintain effective control over financial reporting, it may adversely affect our ability to accurately and timely report our financial results, and may adversely affect investor confidence and business operations.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

During the fourth quarter of 2024, we identified a material weakness in our internal control over financial reporting which relates to cash disbursements. We concluded that this material weakness in our internal control over financial reporting occurred due to our internal controls having not been adequately designed to prevent or timely detect unauthorized cash disbursements. We concluded that the remediation steps taken have been sufficient to remediate this material weakness as of the date of our Annual Report on Form 10-K for the year ended December 31, 2024.

We are focused on designing and implementing effective internal controls measures to improve our evaluation of disclosure controls and procedures, including internal control over financial reporting, and remediating the material weaknesses. We have taken steps to remediate including consulting with experts on technical accounting matters and in the preparation of our financial statements.

However, we cannot assure you that the measures we are taking to remediate the material weaknesses will prevent or avoid potential future material weaknesses. Further, additional weaknesses in our disclosure controls and internal controls over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim financial statements. In such a case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to the listing requirements of Nasdaq, investors may lose confidence in our financial reporting and our stock price may decline as a result.

Risks Related to Taxation

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

Under Section 382 and Section 383 of the Internal Revenue Code of 1986 (IRC), as amended, if a corporation undergoes an "ownership change" (generally defined as one or more shareholders or groups of shareholders who own at least 5 percent of the corporation's equity increasing their equity ownership in the aggregate by a greater than 50 percentage point change (by value) over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2025, we had federal net operating loss carryforwards of approximately $472.7 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above or subject to other limitations, which could potentially result in increased future tax liability to us.

The U.S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service (IRS) and the U.S. Treasury Department. For example, the One Big Beautiful Bill Act (OBBBA) was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. For example, under Section 174 of the IRC, in taxable years beginning after December 31 2021, expenses that are incurred for research and development performed outside the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized. In addition, the OBBBA provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31, 2024. In recent years, many changes to tax laws have been made and changes are likely to continue to occur in the future.

In addition, since the start of the Trump Administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them. You are urged to consult your tax advisor regarding the implications of potential changes in tax laws on an investment in our common stock.

Risks Related to Third Parties

If our collaboration with Regeneron is terminated, or if Regeneron materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition would be materially harmed.

Our financial performance may be significantly affected by our Regeneron collaboration that we have entered into to develop next-generation engineered immune-cell therapeutics with fully human CARs and TCRs directed to disease-specific cell surface antigens in order to enable the precise engagement and killing of tumor cells. Under the Regeneron Agreement, Regeneron paid us a non-refundable upfront payment of $25.0 million and an aggregate of $20.0 million of additional payments for research funding as of September 30, 2026, and we will collaborate with Regeneron to identify and validate targets and develop a pipeline of engineered immune-cell therapeutics for selected targets. Regeneron has the option to obtain development and commercial rights for a certain number of the product candidates developed by the parties, subject to an option payment for each product candidate. On January 28, 2022, we received a payment of $20.0 million from Regeneron for exercise of its option to license exclusive rights to ADI-002, and we completed the transfer of the associated license rights to Regeneron in the first quarter of 2022. If Regeneron exercises its option on a given product candidate, we then have an option to participate in the development and commercialization for such product. If we do not exercise our option, we will be entitled to royalties on any future sales of such products by Regeneron. We did not exercise our option to participate in the development and commercialization of ADI-002. In addition to developing CARs and TCRs for use in novel immune-cell therapies as part of the collaboration, Regeneron will have the right to use these CARs and TCRs in our other antibody programs outside of the collaboration. Regeneron will also be entitled to royalties on any future sales of products developed and commercialized by us under the agreement. If Regeneron were to terminate our collaboration agreement with us, we may not have the resources or skills to replace those of our collaborator, which could require us to seek additional funding or another collaboration that might not be available on favorable terms or at all, and could cause significant delays in development and/or commercialization efforts and result in substantial additional costs to us. Termination of such collaboration agreement or the loss of rights provided to us under such agreement may create substantial new and additional risks to the successful development and commercialization of our products and could materially harm our financial condition and operating results.

Regeneron may change its strategic focus or pursue alternative technologies in a manner that results in reduced, delayed or no revenue to us under the agreement. Regeneron has a variety of marketed products and product candidates either by itself or under collaboration with other companies, including some of our competitors, and the corporate objectives of Regeneron may not be consistent with our best interests. Regeneron may change its position regarding its participation and funding of our and Regeneron joint activities, which may impact our ability to successfully pursue the program.

Our existing and future collaborations will be important to our business. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.

We have entered, and plan to enter, into collaborations with other companies, including our collaboration agreement with Regeneron, our discovery agreement with Twist Bioscience Corporation (Twist), our license and collaboration agreement with CRISPR Therapeutics AG (CRISPR), and our license agreement with the City of Hope, that we believe can provide us with additional capabilities beneficial to our business. For example, the collaboration with Regeneron has provided us with important technologies, expertise and funding for our programs and technology. Under our discovery agreement with Twist, Twist will utilize its proprietary platform technology to assist us with the discovery of novel antibodies related to our gamma delta T cell therapy programs. Further, our license and collaboration agreement with CRISPR provides us with certain propriety gene-editing technology, including the CRISPR/Cas platform, material to supporting the research, development and potential commercialization of ADI-212. Additionally, our non-exclusive license with the City of Hope provides access to their proprietary cytokine expression technology for cellular immunotherapy, which may also be material to the research, development and potential commercialization of ADI-212. We may receive additional technologies, expertise and funding under other collaborations in the future. If any of our existing or potential future collaboration partners does not perform in the manner that we expect or fulfill their responsibilities in a timely manner or at all, the research, clinical development, regulatory approval and commercialization efforts related to the product candidates that are the subject of such collaborations, or that potential future collaboration partner, could be delayed or terminated. This could result in a limited potential to generate future revenue from such product candidates, and our business could be materially and adversely affected.

Our existing collaborations, and any future collaborations we enter into, may pose a number of additional risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may dispute the amounts of payments owed;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license

arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may 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 develop independently, or with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development or commercialization of our product candidates;
- collaborators may dispute ownership or rights in jointly developed technologies or intellectual property;
- collaborators may fail to comply with applicable legal and regulatory requirements regarding the development, manufacture, sale, distribution or marketing of a product candidate or product;
- collaborators with sales, marketing, manufacturing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the sale, marketing, manufacturing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, payment obligations or the preferred course of discovery, development, sales or marketing, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional and burdensome responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend their or our relevant intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation and liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination or cessation, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates, or potentially lose access to the collaborator's intellectual property.

If our collaborations do not result in the successful discovery, development and commercialization of products or if one of our collaborators terminates our agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding or support we expect under these agreements, our development and commercialization of our technology and product candidates could be delayed and we may need additional resources to develop product candidates and our technology. All of the risks relating to product discovery, development, regulatory approval and commercialization described in these risk factors also apply to the activities of our therapeutic collaborators.

In addition to existing collaborations, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for discovery, development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators because, for example, third parties also have rights to allogeneic T cell technologies. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail discovery efforts or the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential manufacture or commercialization, or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our expense. If we elect to fund and undertake discovery, development, manufacturing or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary discovery, development, manufacturing and commercialization activities, we may

not be able to further develop our product candidates, manufacture the product candidates, bring them to market or continue to develop our technology and our business may be materially and adversely affected.

We are subject to certain exclusivity obligations under our agreement with Regeneron.

Under the Regeneron Agreement, both parties have obligations not to research, develop, manufacture or commercialize an immune cell product (ICP) with the same target as one being developed under a research program or commercialized by a party (and royalty bearing under the agreement), for so long as such activities are occurring. These exclusivity obligations are limited to engineered gamma delta immune cells to targets reasonably considered to have therapeutic relevance in cancer. If our collaboration with Regeneron is not successful, including any failure caused by the risks listed in the preceding paragraphs, and the agreement and research programs are not terminated, we may not be able to enter into collaborations with other companies with respect to ICPs and our business could be adversely affected.

The restrictions on internal development under the Regeneron Agreement could lead to delays in our ability to discover and develop gamma delta immune cell therapeutics for targets not covered by the collaboration with Regeneron and loss of opportunities to obtain additional research funding and advance our own technologies separately from the Regeneron collaboration. If we are delayed in our ability to advance our technologies due to the Regeneron Agreement, our business could be harmed.

We rely and will continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We currently depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners to conduct our preclinical studies and clinical trials under agreements with us.

We negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We rely heavily and expect to continue to rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, 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 before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs requirements, and if applicable, cGTP requirements, and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with trial sites, or any CRO that we may use in the future, terminates, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials will involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We currently rely on third parties to manufacture our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if approved.

In addition to our own internal manufacturing capabilities, we currently utilize, and expect to continue to utilize, third parties to manufacture our product candidates. If the field of cell therapy continues to expand, we may encounter increasing competition and costs for these materials and services. Demand for third-party manufacturing in cell therapy may grow at a faster rate than existing capacity, which could disrupt our ability to find and retain third-party manufacturers capable of producing sufficient quantities of our product candidates at an acceptable cost or at all. We have also not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to achieve manufacturing and processing at a commercial scale and therefore may be unable to create an inventory of mass-produced, "off-the-shelf" product to satisfy demands for any of our product candidates.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, we anticipate reliance on a limited number of third-party manufacturers may adversely affect our operations and exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products;
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately;
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products; and
- Our third-party manufacturers could breach or terminate their agreement(s) with us.

If any CDMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CDMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidates according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of our product candidates that such CDMO owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another CDMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Our contract manufacturers would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above. Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Our product candidates require many specialty raw materials, including viral vectors that deliver the targeting moiety and other genes to the product candidate. We currently manufacture through contract manufacturers, some of which have limited resources and experience supporting a commercial product, and such suppliers may not be able to deliver raw materials to our specifications. Those suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and we may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials utilized in the manufacture of our candidates are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. Further, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. We may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on our business.

If we or our third-party suppliers use hazardous, non-hazardous, biological or other materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We and our suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we and our suppliers cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

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

Our internal computer systems and the systems of our CROs, contractors and consultants are vulnerable to cybersecurity threats. Additionally, we operate in a hybrid work environment. As our employees and our business partners' employees work from home and access our systems remotely, we may be subject to heightened security and privacy risks, including the risks of cyber attacks and privacy incidents. Cybersecurity threats include, but are not limited to, social-engineering attacks (including through phishing attacks), business email compromise, online and offline fraud, malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, access attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, and telecommunications failures, among other cybersecurity risks. Threat actors and their techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. We may expend significant resources to try to protect against these threats to our systems. Certain data privacy and security laws, as well as industry best practice standards, may require us to implement and maintain security measures. While we have implemented security measures designed to protect our systems and confidential and sensitive data, there can be no assurance that these measures will be effective. Bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

We and certain of our service providers have in the past and may in the future experience cybersecurity incidents, including incidents related to social engineering, business email compromise, and wire fraud. System failures and security breaches could cause interruptions in our operations, and could result in a disruption of our development programs and our business operations. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed. Other consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Further, our insurance coverage may not be adequate or sufficient in type or amount to protect us from or to mitigate liabilities arising out of our privacy and security practices.

We may not realize the benefits of acquired assets or other strategic transactions.

We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions, and any future strategic transactions depends on the risks and uncertainties involved including:

- unanticipated liabilities related to acquired companies or joint ventures;
- difficulties integrating acquired personnel, technologies, and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- disruption in our relationships with collaborators or suppliers as a result of such a transaction; and possible write-offs or impairment charges relating to acquired businesses or joint ventures.

If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction. Additionally, foreign acquisitions and joint ventures are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries.

Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could have a material adverse effect on our financial condition.

Risks Related to Government Regulation

Risks Related to Regulatory Approval

The FDA 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.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any biological drug product in the United States until we receive approval of a biologics license application (BLA) from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to the EMA or comparable foreign authorities. A BLA must include extensive preclinical and clinical data and sufficient supporting information to establish the product candidate's safety and effectiveness for each desired indication. The 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 allogeneic T cell therapies for autoimmune diseases and cancer. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain marketing approval. Accordingly, 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 in obtaining regulatory approvals, including due to:

- delays in obtaining regulatory authorization to begin a trial, if applicable;
- the need to redesign our study protocols and/or conduct additional studies as may be required by a regulator;
- governmental or regulatory delays and changes in regulation or policy relating to the development and commercialization of our product candidate by the FDA, EMA or other comparable foreign regulatory authorities;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA and other comparable foreign regulatory authorities;
- the availability of financial resources to commence and complete the planned trials;
- negotiating the terms of any collaboration agreements we may choose to initiate or conclude;
- reaching 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 trial sites;
- failure of third-party contractors, such as CROs, or investigators to comply with regulatory requirements, including GCP standards;
- clinical sites deviating from trial protocol or dropping out of a trial;
- delay or failure in obtaining the necessary approvals from regulators or institutional review boards, or IRBs, in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- inability to recruit and enroll suitable patients to participate in a trial;
- having patients complete a trial, including patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or failure to return for post-treatment follow-up;
- addressing any patient safety concerns that arise during the course of a trial;
- inability to add new clinical trial sites;
- varying interpretations of the data generated from our preclinical studies or clinical trials;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties;
- the effect of competing technological and market developments;
- the cost and timing of establishing, expanding and scaling manufacturing capabilities;
- inability to manufacture, or obtain from third parties, sufficient quantities of qualified materials under cGMPs, or if applicable, cGTPs, for the completion of in preclinical studies and clinical trials;
- problems with biopharmaceutical product candidate storage, stability and distribution resulting in global supply chain disruptions;
- the cost of establishing sales, marketing and distribution capabilities for any product candidate for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; or
- potential unforeseen business disruptions or market fluctuations that delay our product development or clinical trials and increase our costs or expenses, such as business or operational disruptions, delays, or system failures due to malware, unauthorized access, terrorism, war, natural disasters, strikes, geopolitical conflicts, restrictions on trade, import or export restrictions, or public health crises.

We could also encounter delays if physicians encounter unresolved ethical issues associated with 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 trials are being conducted or by the FDA, EMA or other regulatory authorities 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 trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or based on a recommendation by the Data Safety Monitoring Committee. 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 may be harmed, and our ability to generate product revenue

may 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.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition from biosimilar products.

The Biologics Price Competition and Innovation Act (BPCIA) established an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The 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 approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA.

We believe that any of our product candidates that are approved in the United States as a biological product under a BLA should qualify for the 12-year period of reference product exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, potentially creating the opportunity for biosimilar competition sooner than anticipated. During this 12-year exclusivity period, a competing product may still be marketed if the FDA approves a full BLA containing the applicant's own preclinical and clinical trial data demonstrating safety, purity and potency. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference product 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. State pharmacy laws govern whether interchangeable products can be readily substituted for the reference product.

The regulatory landscape that will govern our product candidates is uncertain; regulations relating to more established cell therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy and durability of effect must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

Because we are developing novel allogeneic cell immunotherapy product candidates, the regulatory requirements that we will be subject to are not entirely clear. Even with respect to more established products that fit into the category of cell therapies, the regulatory landscape is still developing. For example, regulatory requirements governing cell therapy products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in the regulation of existing cell therapy products.

Complex regulatory environments also exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the EU a special committee called the Committee for Advanced Therapies was established within the EMA in accordance with Regulation No 1394/2007 on advanced-therapy medicinal products (ATMPs) to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field. ATMPs include somatic cell therapy products and tissue engineered products. These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Because the regulatory landscape for our gamma delta CAR T-cell product candidates is new, we may face even more cumbersome and complex regulations than those emerging for cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.

The general approach for FDA approval of a new biologic is for the sponsor to provide dispositive data from one or two well-controlled, Phase 3 clinical studies of the relevant biologic in the relevant patient population. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. We expect registrational trials for our

product candidates to be designed to evaluate the efficacy of the product candidate in an open-label, non-comparative, two-stage, pivotal, multicenter, single-arm clinical trial in patients who have exhausted available treatment options. If the results are sufficiently compelling, we intend to discuss with the FDA submission of a BLA for the relevant product candidate. However, the process of clinical development is inherently uncertain and we do not have any agreement or guidance from the FDA that our future regulatory development plans are acceptable or will be sufficient to support submission of a BLA. For example, we may seek an accelerated approval pathway for our one or more of our product candidates from the FDA, EMA or comparable foreign regulatory authorities. If we decide to submit an application for accelerated approval, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all.

The FDA may grant accelerated approval for our product candidates that meet the criteria for accelerated approval. As a condition for accelerated approval, the FDA may require a sponsor of a drug or biologic receiving accelerated approval to perform post marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is permitted to require that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of accelerated approval was granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. Even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval. Further, the standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA, EMA or other regulatory agencies requesting additional studies to evaluate our product candidate relative to the new products.

Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications, or that a related companion diagnostic test is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities will inspect our manufacturing facility (or our CDMO's facility) and may not find it acceptable; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We may seek orphan drug designation for some or all of our product candidates across various indications, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. In order to obtain orphan drug designation, the request must be made before submitting a BLA. In the U.S., orphan

drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval of that particular product for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic (meaning, a product with the same principal molecular structural features) for the same approved use or indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other biologics that do not have the same principal molecular structural features for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or if a subsequent applicant demonstrates clinical superiority over our products.

We may seek orphan drug designation for some or all of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products, if approved. In addition, although we may seek orphan drug designation for other product candidates, we may never receive such designations. Further, the FDA may further reevaluate its regulations and policies under the Orphan Drug Act. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

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

We have received fast track designation for prula-cel for the treatment of relapsed/refractory Class III or IV LN, refractory SLE with extrarenal involvement, and SSc. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical needs for this condition, the product candidate sponsor may apply for fast track designation for a particular indication. We may seek fast track designation for certain of our product candidates, but there is no assurance that the FDA will grant this status to any of our product candidates. Marketing applications filed by sponsors of product candidate with fast track designation may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant fast track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a fast track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Regenerative Medicine Advanced Therapy (RMAT) designation, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek RMAT designation for one or more of our product candidates. In 2017, the FDA established the RMAT designation to expedite review of a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates that the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. There is no assurance that we will be able to obtain RMAT designation for any of our product candidates. RMAT designation does not change the FDA's standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

Positive results from early preclinical studies and clinical trials are not necessarily predictive of the results of any future clinical trials of our product candidates, and may change as more patient data becomes available and is subject to audit and verification procedures that could result in material changes in the final data. If we cannot replicate the positive results from our earlier preclinical studies and clinical trials of our product candidates in our future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidate.

From time to time, we may publish interim, top-line or preliminary results from our preclinical studies or clinical trials. Such clinical results are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We may also make assumptions, estimations, calculations and conclusions as part of our analyses of preliminary or top-line data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously announced. As a result, interim, "top-line," and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. It is also difficult to predict the timing of announcing interim results.

Accordingly, any positive results from our preclinical studies and ongoing and future clinical trials of our product candidates may not necessarily be predictive of the results from required later clinical trials. Similarly, even if we are able to complete our planned preclinical studies or any future clinical trials according to our current development timeline, the positive results from such preclinical studies and clinical trials may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidate performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or similar regulatory approval.

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

If the clinical updates, or the interim, "top-line", or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

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

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. 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 United States, 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 United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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

jurisdictions. Obtaining foreign 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.

Even if we receive regulatory approval of our product candidates, we will 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 post-market surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy (REMS), in order 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. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, quality control, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and record keeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers are required to register establishments with the FDA and certain state agencies, and will be subject to continual review and unannounced inspections by the FDA and state agencies to assess compliance with cGMPs and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information.

Further, even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. We will also be required to comply with FDA's promotion and advertising rules, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturers' communications on the subject of off-label use of their products. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, FDA Form 483s, untitled letters, warning letters or holds on 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; and
- injunctions or the imposition of civil or criminal penalties.

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 or executive action, either in the United States 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 and we may not achieve or sustain profitability.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community, adversely affecting our ability to achieve our commercial and financial projections.

The use of engineered gamma delta T cells as potential treatments for autoimmune diseases and cancer is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. We expect physicians, including rheumatologists, nephrologists and oncologists, to be particularly important to the market acceptance of our products and we may not be able to educate them on the benefits of using our product candidates for many reasons. Additional factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, EMA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

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

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because our product candidates represent new approaches to the treatment of autoimmune diseases and cancer, we cannot accurately estimate the potential revenue from our product candidates. For further discussion on coverage and reimbursement matters, see the section entitled "*Business—Government Regulation and Product Approval Coverage, Pricing and Reimbursement*" in our Annual Report on Form 10-K for the year ended December 31, 2025.

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

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. 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.

Obtaining coverage and reimbursement 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. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are 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. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, Centers for Medicare and Medicaid Services (CMS) revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payers rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payers and reduce the willingness of physicians to use our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Because our product candidate may have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidate. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. Additional state and federal healthcare reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for certain pharmaceutical products or additional pricing pressures. Specifically, there have been several United States Congressional inquiries and federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. Increased efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidate. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other EU member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure

on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The advancement of healthcare reform may negatively impact our ability to sell our product candidates, if approved, profitably.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our product candidates, if approved, profitably. For further discussion on healthcare reform matters, see the section entitled "*Business – Government Regulation and Product Approval – Healthcare Reform*" in our Annual Report on Form 10-K for the year ended December 31, 2025.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices, which has resulted in several U.S. Congressional inquiries and federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs, and review the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act of 2022 (the "IRA"), for example, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries to $2,000 starting in 2025, eliminating the prescription drug coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of an HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs were previously exempted from the Medicare drug price negotiation program; however, this exemption was restricted to drugs with only one orphan designation and for which the only approved indication is for that disease or condition. If a product received multiple orphan designations or had multiple approved indications, it would not qualify for the orphan drug exemption. Under the One Big Beautiful Bill Act of 2025, this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan designations or indications, are exempt from the Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

On April 15, 2025, the Trump Administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called "pill penalty" under the Inflation Reduction Act that creates a distinction between small molecule and large molecule products for purposes of determining when a drug may be eligible for drug price negotiation. On May 12, 2025, the Trump Administration published Executive Order 14297, "Delivering MFN Prescription Drug Pricing to American Patients" which generally, among other things, directs the federal government to establish and communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the Administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the most-favored-nation lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Notably, a similar "MFN" pricing rule enacted under the first Trump Administration was subject to an injunction resulting from judicial challenges to the rule, which was formally rescinded by the former Biden Administration in August 2021. Recent CMS proposals, including the GLOBE, GUARD, and GENEROUS, could materially impact the Company's revenue.

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. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical and biologics pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in various congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our product candidates or additional pricing pressures. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects. 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 it believes 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.

In addition, the U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States 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, our business could be materially harmed.

Risks Related to Intellectual Property

Risks Related to Our Intellectual Property

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and license agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Additional patent applications have been filed, and we anticipate additional patent applications will be filed, both in the United States and in other countries, as appropriate. However, we cannot predict:

- if and when patents will issue;
- the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

Composition of matter patents for biological and pharmaceutical products such as CAR-based product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications covering composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO), or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the patentability, validity, enforceability or scope thereof, for example through inter partes review (IPR) post-grant review or ex parte reexamination before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions, which may result in such patents being cancelled, narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. United States patent applications containing or that at any time contained a claim not entitled to a priority date before March 16, 2013 are subject to the "first to file" system implemented by the America Invents Act (2011).

This first to file system will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that it was the first to file any patent application related to our product candidates. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For United States applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the America Invents Act, which brought into effect significant changes to the United States patent laws, including new procedures for challenging patent applications and issued patents.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

We may require access to additional intellectual property to develop our current or future product candidates. Accordingly, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

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

Competitors may infringe our patents or the patents of our 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 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.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other 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.

The lives of our patents may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may in the future be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Issued patents covering our product candidates could be found unpatentable, 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 United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include IPR, ex parte re-examination and post grant review in the United States, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of unpatentability, invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of unpatentability, 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.

Risks Related to Third Party Intellectual Property

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We depend substantially on our license agreements with Regeneron, CRISPR and City of Hope. These licenses may be terminated upon certain conditions. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. To the extent these licensors fail to meet their obligations under their license agreements, which we are not in control of, we may lose the benefits of our license agreements with these licensors. In the future, we may also enter into additional license agreements that are material to the development of our product candidates.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those related to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Trade secrets, however, may be difficult to protect. Although we require all of our employees to assign their inventions to us, and require all of our employees and key consultants who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

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

Our commercial success depends in part on us avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

We are aware of United States and foreign patents held by a third party relating to gamma delta T cell expansion protocols and related compositions which, on information and belief, are invalid and/or not infringed. In the event that these patents are successfully asserted against our product candidates, such as prula-cel, or the use of our precursor cells in manufacture of these product candidates, such litigation may negatively impact our ability to commercialize these product candidates in such jurisdictions. We are also aware of several United States and foreign patents held by third parties relating to certain CAR compositions of matter, methods of making and methods of use which, on information and belief, are invalid and/or not infringed. Nevertheless, third parties may assert that we infringe their patents or are otherwise employing their proprietary technology without authorization and may sue us. Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when prula-cel, or another CAR-based product candidate is approved by the FDA, third parties may then seek to enforce their patents by filing a patent infringement lawsuit against us. Patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. We may not be able to prove in litigation that any patent enforced against us is invalid and/or not infringed.

Additionally, there may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held not infringed, unpatentable, invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held not infringed, unpatentable, invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

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

Risks Related to Intellectual Property Laws

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Recent United States Court of Appeals for the Federal Circuit and 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 United States 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.

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

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

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. 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 these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Ownership of Our Common Stock

Risks Related to Ownership Generally

The trading price of our common stock is highly volatile, which could result in substantial losses for purchasers of our common stock. Securities class action or other litigation involving our company or members of our management team could also substantially harm our business, financial condition and results of operations.

Our stock price is highly volatile. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. In addition, if the market for pharmaceutical and biotechnology stocks or the broader stock market continues to experience a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition or results of operations. As a result of this volatility, you may not be able to sell your common stock at or above the purchase price and you may lose some or all of your investment. The market price for our common stock may be influenced by many factors, including:

- the success of existing or new competitive products or technologies;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the timing and results of clinical trials of prula-cel;
- our ability to obtain FDA clearance of additional INDs for prula-cel in autoimmune indications;

- the initiation, timing and results of clinical studies of ADI-212;
- commencement or termination of collaborations for our development programs;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop additional product candidates or products;
- issues or delays regarding the manufacturing of our product candidates and, if approved, products by us or by our third-party suppliers;
- actual or anticipated changes in estimates as to financial results or development timelines;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. We have been, and may in the future be, subject to securities litigation related to corporate governance matters determined in good faith by our board of directors, including the stock option repricing in August 2023 in accordance with the terms of our 2015 Plan and 2018 Plan. Even if the allegations against us are unfounded or we ultimately are not held liable, we may experience related negative publicity resulting in damage to our reputation. Further, the costs to defend ourselves may be significant and the litigation may subject us to substantial settlements, fines, penalties or judgments against us and may consume management's bandwidth and attention, some or all of which may negatively impact our financial condition and results of operations.

An active trading market for our common stock may not be sustained. If an active trading market is not sustained, our ability to raise capital in the future may be impaired.

Our common stock began trading on The Nasdaq Global Market on January 26, 2018 and now trades on The Nasdaq Capital Market under the symbol "ACET." There is a risk that an active trading market for our shares may not be sustained, which could put downward pressure on the market price of our common stock and thereby affect your ability to sell shares you purchased. An inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and impair our ability to acquire other companies or technologies by using our shares as consideration.

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

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

Risks Related to Market Uncertainties

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, volatile interest rates, rising and fluctuating inflation rates, reduced corporate profitability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. U.S. debt ceiling and budget deficit concerns have increased the possibility of additional credit-rating downgrades and economic slowdowns, or a recession in the United States. Although U.S. lawmakers passed legislation to raise the federal debt ceiling on multiple occasions, ratings agencies have lowered or threatened to lower the long-term sovereign credit rating on the United States. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions. In addition, inflation rates in the U.S. have recently increased to levels not seen in decades.

We believe that the state of global economic conditions are particularly volatile and uncertain and may negatively impact our ability to conduct clinical trials on the scale and timelines anticipated. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business or political environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make obtaining any necessary debt or equity financing more difficult, more costly and more dilutive. For example, as a result of political, social, and economic instability abroad, including as a result of armed conflict, war or threat of war, in particular, the current conflict between Russia and Ukraine, including resulting sanctions, terrorist activity and other security concerns in general, there could be a significant disruption of global financial markets, impairing our ability to raise capital when needed on acceptable terms, if at all. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget. To the extent that our profitability and strategies are negatively affected by downturns or volatility in general economic conditions, our business and results of operations may be materially adversely affected.

Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. For instance, rising interest rates have impacted our net income. Recent supply chain constraints have led to higher inflation, which, if sustained, could have a negative impact on our product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new therapeutic products may be negatively affected. Current capital market conditions, including the impact of inflation, have increased borrowing rates and can be expected to significantly increase our cost of capital as compared to prior periods and could also affect our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third-party suppliers and manufacturers to manufacture clinical trial materials for our product candidates.

Risks Related to our Charter and Bylaws

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

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

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;

- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of not less than 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors;
- a requirement of approval of not less than 75% of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

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

Our amended and restated bylaws provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our amended and restated bylaws specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our director, officer or other employee to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or amended and restated bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine (Delaware Forum Provision); provided, however, that the Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. This choice of forum provision contained in our amended and restated bylaws will not apply to any causes of action arising under the Securities Act or the Exchange Act. 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 amended and restated bylaws described above; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' bylaws or certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated bylaws to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

General Risk Factors

We are a Smaller Reporting Company (SRC) and the reduced disclosure requirements applicable to SRCs may make our common stock less attractive to investors.

We are considered a SRC under Rule 12b-2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive

because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock prices may be more volatile. We will remain a smaller reporting company for as long as (i) the market value of our common stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700.0 million as of the prior June 30.

We have broad discretion over the use of our cash, cash equivalents and short-term investments and may not use them effectively.

Our management has broad discretion to use our cash, cash equivalents and short-term investments to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending our use to fund operations, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We have never declared nor paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. In addition, the terms of any future debt or credit agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the future clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend themselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize any product candidate.

Our inability to obtain sufficient product liability insurance at an acceptable cost 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 we may be subject to a product liability claim for which we have no coverage. Assuming we obtain clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceeds 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. Even if our agreements with any future corporate collaborators entitle it to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act of 1933, as amended (Securities Act) would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

On March 6, 2025, we filed a registration statement on Form S-3 (File No. 333-285609) with the SEC, which was declared effective on March 14, 2025 (2025 Shelf Registration Statement), in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof for the purposes of selling, from time to time, our common stock, debt securities or other equity securities in one or more offerings. Under the 2025 Shelf Registration Statement and a prospectus supplement filed on October 7, 2025, we completed an underwritten registered direct offering of 4,375,062 shares of our common stock, and, in lieu of common stock to certain investors, pre-funded warrants to purchase 625,000 shares of common stock. The shares of common stock were sold at a price of $16.00 per share and the pre-funded warrants were sold at a price of $15.9984 per pre-funded warrant, which represents the pre share price of each share of common stock minus the $0.0016 per share exercise price for each pre-funded warrant. We received $80.0 million in aggregate gross proceeds from the offering, before deducting underwriting discounts and commissions and offering expenses. As a result of this offering, our stockholders experienced significant dilution. If we sell, or the market perceives that we intend to sell, substantial amounts of our common stock under the 2025 Shelf Registration Statement or otherwise, the market price of our common stock could decline significantly.

On March 12, 2026, we filed a registration statement on Form S-3 (File No. 333-294265) with the SEC, which was declared effective on March 23, 2026 (2026 Shelf Registration Statement), in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof for the purposes of selling, from time to time, our common stock, debt securities or other equity securities in one or more offerings. If we sell, or the market perceives that we intend to sell, substantial amounts of our common stock under the 2026 Shelf Registration Statement or otherwise, the market price of our common stock could decline significantly.

We have also filed registration statements on Form S-8 registering the issuance of shares of common stock issued or reserved for future issuance under our equity compensation plans. Shares registered under these registration statements on Form S-8 can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described above. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

In addition, certain of our employees, executive officers, and directors may enter into Rule 10b5-1 trading plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5-1 trading plan, a broker executes trades pursuant to parameters established by the employee, director, or officer when entering into the plan, without further direction from the employee, officer, or director. A Rule 10b5-1 trading plan may be amended or terminated in some circumstances. Our employees, executive officers, and directors also may buy or sell additional shares outside of a Rule 10b5-1 trading plan when they are not in possession of material, nonpublic information.

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

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(c) None of our directors or "officers," as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, adopted or terminated a Rule 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement, as defined in Item 408(c) of Regulation S-K, during the fiscal quarter covered by this report.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (as currently in effect) (incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 12, 2026).
3.2	Amended and Restated Bylaws of the Registrant (as currently in effect) (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on January 30, 2018).
4.1	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on October 7, 2025).
4.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on April 28, 2026).
10.1#*	Form of Stock Option Cancellation Agreement
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

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

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

SIGNATURES

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

ADICET BIO, INC.

Date: November 5, 2026

By: /s/ Chen Schor
Chen Schor
President and Chief Executive Officer
(Principal executive officer)

Date: November 5, 2026

By: /s/ Nick Harvey
Nick Harvey
Chief Financial Officer
(Principal financial and accounting officer)

STOCK OPTION CANCELLATION AGREEMENT

This STOCK OPTION CANCELLATION AGREEMENT (the "Agreement") is made and entered into as of ____ ___, 2026 (the "Effective Date"), by and between _____ (the "Optionee") and Adicet Bio, Inc., a Delaware corporation (the "Corporation").

WHEREAS, the Corporation has previously granted to the Optionee a stock option to purchase 195,898 shares (the "Option") of the Corporation's common stock, $0.0001 par value per share, as an inducement pursuant to Rule 5635(c)(4) of the Marketplace Rules of The Nasdaq Stock Market LLC;

WHEREAS, the Optionee believes it to be in the Optionee's best interest as an employee of the Corporation and in the best interest of the Corporation and its stockholders for the Optionee to voluntarily surrender and cancel certain shares outstanding subject to the Option that the Optionee presently holds, as identified on Exhibit A hereto (the "Cancelled Option"); and

WHEREAS, the Optionee desires to surrender the Cancelled Option for cancellation without receiving any cash, equity awards or other consideration and without any expectation to receive, and without imposing any obligation on the Corporation to pay or grant, any cash, equity awards or other consideration presently or in the future in connection with the cancellation of such Cancelled Option.

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth herein, the parties hereto, intending to be legally bound, the parties hereby agree as follows:

1. **Surrender and Cancellation of Option**. The Optionee hereby surrenders the Cancelled Option for cancellation, and the Corporation hereby accepts such surrender and cancellation, effective as of the Effective Date. By execution of this Agreement, the parties have taken all steps necessary to cancel the Cancelled Option.

2. **No Expectation or Obligation**. The Optionee and the Corporation acknowledge and agree that the surrender and cancellation of the Cancelled Option described herein shall be without any expectation of the Optionee to receive, and without imposing any obligation on the Corporation to pay or grant, any cash, equity awards or other consideration presently or in the future in connection with the surrender and cancellation of such Cancelled Option.

3. **Miscellaneous**.

   3.1 Successor and Assigns. This Agreement shall be binding upon, and inure to the benefit of, both parties and their respective successors and assigns.

   3.2 Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the laws of the State of Delaware, without regard to any choice of law principle that would dictate the application of the law of another jurisdiction.

   3.3 Counterparts. This Agreement may be executed in several counterparts and all documents so executed shall constitute one agreement, binding on each of the parties hereto, notwithstanding that both of the parties did not sign the original or the same counterparts.

   3.4 Headings. The headings of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

   3.5 Severability. In the event that any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

   3.6 Entire Agreement. This Agreement constitutes the entire agreement between the parties and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement. The Company and the Optionee have made no promises, agreements, conditions, or understandings relating to this subject matter, either orally or in writing, that are not included in this Agreement.

[Signature Page to Follow]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Effective Date.

ADICET BIO, INC.

By: _____
Name: _____
Title: _____
Date: _____

OPTIONEE:

Agreed and acknowledged by:

_____

_____

Date: _____

[SIGNATURE PAGE TO THE STOCK OPTION CANCELLATION AGREEMENT]

EXHIBIT A

Cancelled Option

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Chen Schor, certify that:

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

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

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

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

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

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

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

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

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

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

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

/s/ Chen Schor

Chen Schor
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2026

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Nick Harvey, certify that:

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

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

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

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

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

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

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

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

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

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

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

/s/ Nick Harvey
Nick Harvey
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: November 5, 2026

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Adicet Bio, Inc. (the "Company") for the quarter ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, that, to the best of their knowledge:

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

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

/s/ Chen Schor
Chen Schor
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2026

/s/ Nick Harvey
Nick Harvey
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: November 5, 2026