

**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 March 31, 2023

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**

(State or other jurisdiction of  
incorporation or organization)

**200 Berkeley Street, 19th Floor  
Boston, MA**

(Address of principal executive offices)

**81-3305277**

(I.R.S. Employer  
Identification No.)

**02116**

(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 Global Market

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 May 5, 2023, the registrant had 42,957,586 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 expense as we build our capabilities.
- Our business is highly dependent on the success of ADI-001. If we are unable to obtain regulatory approval for ADI-001 and effectively commercialize ADI-001 for the treatment of patients in our approved indications, our business would be significantly harmed.
- Our gamma delta T cell candidates represent a novel approach to cancer treatment 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 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) 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 have not yet commenced manufacturing operations at our manufacturing facility and 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 ADI-001. 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.
- Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.
- A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and operations.
- The current conflict between Russia and Ukraine may increase the likelihood of supply interruptions which could impact our ability to find the materials we need to make our product candidates.
- Failure to achieve and maintain effective internal control over financial reporting 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.
- 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.
- 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.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.
- Our business is affected by macroeconomic conditions, including any potential recession, rising inflation, interest rates and supply chain constraints.

## 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 ADI-001 in non-Hodgkin’s lymphoma (NHL), including the ability to successfully complete our Phase 1 clinical trial and the period during which the results of the trial will become available;
- our expectations regarding our additional internal gamma delta T cell therapy programs, including ADI-925, in preclinical development and our ability to develop other oncology product candidates in our research pipeline;
- our expectations regarding the availability, timing and announcement of data from our Phase 1 clinical trial;
- our expectations regarding discussions with the FDA and the European Medicines Agency (EMA) of a potential path to support Biologics License Application (BLA) and Marketing Authorization Application (MAA) for ADI-001;
- the anticipated timing of our submission of IND applications or equivalent regulatory filings and initiation of future clinical trials, including the timing of the anticipated results;
- the impact of the COVID-19 pandemic on our continuing operations, clinical development plans, including the timing of initiation and completion of studies or trials, financial forecasts and expectations, and other matters related to our business and operations;
- our expectations regarding the impact of unstable market and economic conditions, including impacts of inflation 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 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 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 and cash equivalents;
- 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.

## Item 1. Consolidated Financial Statements (Unaudited).

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

	March 31, 2023	December 31, 2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 231,640	\$ 257,656
Prepaid expenses and other current assets	3,168	3,382
Total current assets	234,808	261,038
Property and equipment, net	29,886	28,710
Operating lease right-of-use asset	19,708	20,269
Goodwill	19,462	19,462
Other non-current assets	1,110	1,211
Total assets	\$ 304,974	\$ 330,690
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,747	\$ 4,404
Accrued and other current liabilities	12,399	12,811
Operating lease liability	2,949	2,492
Total current liabilities	18,095	19,707
Operating lease liability, net of current portion	20,548	18,531
Other non-current liabilities	116	114
Total liabilities	38,759	38,352
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized as of March 31, 2023 and December 31, 2022, respectively; none issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	—	—
Common stock, \$0.0001 par value, 150,000,000 shares authorized as of March 31, 2023 and December 31, 2022, respectively; 42,957,431 and 42,954,820 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	4	4
Additional paid-in capital	535,206	530,448
Accumulated deficit	(268,995)	(238,114)
Accumulated other comprehensive income	—	—
Total stockholders' equity	266,215	292,338
Total liabilities and stockholders' equity	\$ 304,974	\$ 330,690

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Revenue—related party	\$ —	\$ 24,990
Operating expenses:		
Research and development	26,756	13,483
General and administrative	6,566	6,801
Total operating expenses	<u>33,322</u>	<u>20,284</u>
Income (loss) from operations	(33,322)	4,706
Interest income	2,666	32
Interest expense	(19)	(18)
Other expense, net	(206)	(102)
Income (loss) before income tax provision	<u>(30,881)</u>	<u>4,618</u>
Income tax provision	—	—
Net income (loss)	<u>\$ (30,881)</u>	<u>\$ 4,618</u>
Net income (loss) per share attributable to common stockholders, basic	<u>\$ (0.72)</u>	<u>\$ 0.12</u>
Net income (loss) per share attributable to common stockholders, diluted	<u>\$ (0.72)</u>	<u>\$ 0.10</u>
Weighted-average common shares used in computing net income (loss) per share attributable to common stockholders, basic	<u>42,955,688</u>	<u>39,823,246</u>
Weighted-average common shares used in computing net income (loss) per share attributable to common stockholders, diluted	<u>42,955,688</u>	<u>45,958,941</u>

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	Total Stockholders' Equity
	Shares	Amount			
<b>Balance at December 31, 2022</b>	42,954,820	\$ 4	\$ 530,448	\$ (238,114)	\$ 292,338
Issuance of common stock upon exercise of stock options	713	—	3	—	3
Issuance of common stock upon vesting of restricted stock	3,205	—	—	—	—
Shares withheld for taxes	(1,307)	—	(10)	—	(10)
Stock-based compensation expense	—	—	4,765	—	4,765
Net loss	—	—	—	(30,881)	(30,881)
<b>Balance at March 31, 2023</b>	<u>42,957,431</u>	<u>\$ 4</u>	<u>\$ 535,206</u>	<u>\$ (268,995)</u>	<u>\$ 266,215</u>



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

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
<b>Balance at December 31, 2021</b>	39,736,914	\$ 4	\$ 471,449	\$ (168,324)	\$ 303,129
Issuance of common stock upon exercise of stock options	10,099	—	93	—	93
Issuance of common stock upon vesting of restricted stock	224,000	—	—	—	—
Shares withheld for taxes	(85,197)	—	(1,106)	—	(1,106)
Stock-based compensation expense	—	—	4,350	—	4,350
Net income	—	—	—	4,618	4,618
<b>Balance at March 31, 2022</b>	<u>39,885,816</u>	<u>\$ 4</u>	<u>\$ 474,786</u>	<u>\$ (163,706)</u>	<u>\$ 311,084</u>

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ (30,881)	\$ 4,618
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization expense	1,254	352
Noncash lease expense	561	645
Stock-based compensation expense	4,765	4,350
Loss on disposal of property, plant, and equipment	—	18
Amortization of deferred debt issuance costs	17	18
Changes in operating assets and liabilities:		
Accounts receivable - related party	—	185
Prepaid expenses and other current assets	214	1,077
Other non-current assets	84	117
Accounts payable	(2,333)	(612)
Contract liabilities — related party	—	(4,805)
Operating lease liability	2,474	(361)
Accrued and other current and non-current liabilities	(249)	(1,497)
Net cash provided by (used in) operating activities	<u>(24,094)</u>	<u>4,105</u>
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(1,915)	(2,632)
Net cash provided by (used in) investing activities	<u>(1,915)</u>	<u>(2,632)</u>
<b>Cash flows from financing activities</b>		
Proceeds from exercise of stock options	3	94
Taxes withheld and paid related to net share settlement of equity awards	(10)	(1,106)
Deferred issuance costs	—	(122)
Net cash provided by (used in) financing activities	<u>(7)</u>	<u>(1,134)</u>
Net change in cash, cash equivalents and restricted cash	(26,016)	339
Cash, cash equivalents and restricted cash, at the beginning of period	257,656	277,694
Cash, cash equivalents and restricted cash, at the end of period	<u>\$ 231,640</u>	<u>\$ 278,033</u>
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	\$ 231,640	\$ 277,883
Restricted cash	—	150
Cash, cash equivalents and restricted cash	<u>\$ 231,640</u>	<u>\$ 278,033</u>
<b>Supplemental cash flow information</b>		
<b>Supplemental disclosures of noncash investing and financing activities</b>		
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 1,081	\$ 1,481

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

## **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 cancer. The Company is advancing a pipeline of “off-the-shelf” gamma delta T cells, engineered with chimeric antigen receptors (CARs) and adaptors (CAbs), to enhance selective tumor targeting and facilitate innate and adaptive anti-tumor immune response for durable activity in patients. The Company’s approach to activate, engineer, and manufacture allogeneic gamma delta T cell product candidates derived from the peripheral blood cells of unrelated donors allows it to generate new product candidates in a rapid and cost-efficient manner.

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.

### **Liquidity**

The Company has incurred significant net operating losses and negative cash flows from operations and has an accumulated deficit of \$269.0 million as of March 31, 2023. 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 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 under a registration statement on Form S-3 (File No. 333-254193) (2021 Shelf Registration Statement) filed with the U.S. Securities and Exchange Commission (the SEC), which was declared effective on March 30, 2021. In August 2022, pursuant to the Sales Agreement and subject to the limitations thereof, the Company sold an aggregate of 2,611,723 shares of common stock at \$17.23 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 Company expects that its cash and cash equivalents, including the net proceeds it received from its ATM offering, will be sufficient to fund its forecasted operating expenses, capital expenditure requirements and debt service payments for at least the next twelve months from the issuance of these interim consolidated financial statements.

All of the Company’s revenue to date has been generated from a collaboration and license 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.

## **2. Summary of Significant Accounting Policies**

### ***Basis of Presentation***

The unaudited interim consolidated financial statements and related disclosures have been prepared in conformity with accounting principles generally accepted in the United States of America (United States GAAP or GAAP).

### ***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, 2022. There have been no material changes to the significant accounting policies during the three months ended March 31, 2023.

### ***Unaudited Interim Financial Information***

The accompanying unaudited consolidated financial statements as of March 31, 2023, and for the three months ended March 31, 2023, have been prepared by the Company, pursuant to the rules and regulations of the SEC, for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with 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, 2022. 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 March 31, 2023 and consolidated results of operations for the three months ended March 31, 2023 and 2022 and consolidated cash flows for the three months ended March 31, 2023 and 2022 have been made. The results of operations for the three months ended March 31, 2023 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2023.

### ***Concentration of Credit Risk***

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents. The Company's cash and cash equivalents are held at one financial institution in the U.S. and one financial institution in Israel and such amounts may, at times, exceed insured limits. The Company invests its cash equivalents in money market funds. The Company limits its credit risk associated with cash equivalents 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 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 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 June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. This ASU replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes will result in earlier recognition of credit losses. For SEC filers that are eligible to be smaller reporting companies, this ASU is effective for fiscal years beginning after December 15, 2022, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted the provisions of ASU 2016-13 in the first quarter of 2023. There was no impact to the consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* (ASU 2017-04). The new guidance simplifies the subsequent measurement of goodwill by removing the second step of the two-step impairment test. The amendment requires an entity to perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. SEC filers that are eligible to be smaller reporting companies should adopt the amendments in this update for its annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2022. The amendment should be applied on a prospective basis. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company adopted the provisions of ASU 2017-04 in the first quarter of 2023. The impact on its consolidated financial statements and related disclosures was not material.

### **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 level 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):

	March 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (1) (2)	\$ 228,727	\$ —	\$ —	\$ 228,727
Total fair value of assets	\$ 228,727	\$ —	\$ —	\$ 228,727

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (1) (2)	\$ 75,701	\$ —	\$ —	\$ 75,701
Total fair value of assets	\$ 75,701	\$ —	\$ —	\$ 75,701

(1) Included in cash and cash equivalents in the consolidated balance sheets.

(2) Money market funds are included within Level 1 of the fair value hierarchy because they are valued using quoted market prices.

#### 4. Prepaid Expenses and Other Current Assets

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

	March 31, 2023	December 31, 2022
Prepaid insurance	\$ 974	\$ 1,251
Prepaid software subscription and licensing fees	297	529
Interest receivable	567	435
Prepayments to CROs	273	427
Prepaid maintenance	445	295
Prepayments to CDMOs	101	65
Other prepaid expenses and current assets	511	380
Total prepaid expenses and other current assets	\$ 3,168	\$ 3,382

#### 5. Property and Equipment, net

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

	Useful life (in years)	March 31, 2023	December 31, 2022
Laboratory equipment	3	\$ 10,614	\$ 7,503
Leasehold improvements	Lesser of useful life or lease term	25,965	19,959
Furniture and fixtures	3	951	184
Construction in progress	—	1,833	9,292
Computer equipment	3	177	172
Software	3	352	353
		39,892	37,463
Less: Accumulated depreciation and amortization		(10,006)	(8,753)
Property and equipment, net		\$ 29,886	\$ 28,710

Depreciation and amortization expense was \$1.3 million and \$0.4 million for the three months ended March 31, 2023 and 2022, respectively. The increase in expense is primarily due to the completion of the Company's good manufacturing practice (GMP) cell processing and vector manufacturing suite at the Company's office in Redwood City, California (1000 Bridge Parkway) in February 2023.

Construction in progress has decreased by \$7.5 million during the three months ended March 31, 2023, compared to the balance at December 31, 2022 due to the Company's completion of the Company's GMP cell processing and vector manufacturing suite in February 2023. The remaining \$1.8 million in construction in progress as of March 31, 2023 is primarily related to lab and computer equipment not yet placed into service.

## 6. Accrued and Other Current Liabilities

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

	March 31, 2023	December 31, 2022
Accrued compensation	\$ 3,755	\$ 5,703
Accrued CDMO costs	5,136	4,390
Accrued professional services	1,197	1,356
Accrued other research and development expenses	519	674
Accrued CRO costs	1,720	657
Accrued other liabilities	72	31
Total accrued and other liabilities	\$ 12,399	\$ 12,811

## 7. Term Loan

On April 28, 2020, the Company entered into a Loan and Security Agreement (the Loan Agreement) as amended on July 8, 2020, September 14, 2020, September 15, 2020, October 21, 2022 and December 2, 2022 (the 2022 Amendment) with Pacific Western Bank (PacWest).

On March 13, 2023, the Company and PacWest executed a letter agreeing that, notwithstanding the covenants included in the 2022 Loan Amendment, until June 30, 2023 (i) the Company and its subsidiaries will not be required to maintain the lesser of \$200 million or seventy percent (70%) of its combined balances in demand deposit accounts, money market funds and/or insured cash sweep (ICS) accounts with PacWest and (ii) the Company must maintain its combined balances at PacWest or its affiliates, including Pacific Western Asset Management (the Letter). At all times following June 30, 2023, the Company will again be required to comply with the terms of the 2022 Loan Amendment. Upon executing this letter, the Company wired \$187.2 million from its insured cash sweep (ICS) accounts at PacWest to Pacific Western Asset Management who subsequently invested the funds into money market funds held in custody with U.S. Bank National Association. The Company's remaining balance of funds held in demand deposit accounts and ICS accounts with PacWest is approximately \$2.9 million as of March 31, 2023.

As of March 31, 2023, the Company has \$10.6 million available under the Loan Agreement. Additionally, as of the date of this Quarterly Report on Form 10-Q, the Company is in compliance with such covenants and had no indebtedness outstanding under the Loan Agreement.

## 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 March 31, 2023. 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 March 31, 2023.

On January 28, 2022, Regeneron exercised its option to license the exclusive, worldwide rights to ADI-002, an allogeneic gamma delta chimeric antigen receptor (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 three months ended March 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.

As of March 31, 2023 and 2022, there were no contract assets related to the Regeneron Agreement. The following tables present changes in the Company's contract liabilities for the three months ended March 31, 2023 and 2022 (in thousands):

<b>Three Months Ended March 31, 2023</b>	<b>Balance at Beginning of Period</b>	<b>Deductions</b>	<b>Balance at End of Period</b>
Contract liability	\$ —	\$ —	\$ —

  

<b>Three Months Ended March 31, 2022</b>	<b>Balance at Beginning of Period</b>	<b>Deductions (1)</b>	<b>Balance at End of Period</b>
Contract liability	\$ 4,805	\$ (4,805)	\$ —

(1) Deductions to contract liabilities relate to deferred revenue recognized as revenue during the reporting period.

### ***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 March 31, 2023, the Company has incurred and expensed \$1.0 million related to project initiation fees, technology access fees and projects fees as research and development expense related to this agreement.

## **9. License, Funding and Other Agreements**

### ***National Institute of Health***

In May 2019, the Company was awarded a 5-year grant for up to \$1.5 million from the National Institutes of Health (the NIH) to study RTB101 and the regulation of antiviral immunity in the elderly. The Company is entitled to use the award solely to conduct the research. The Company is solely responsible for commencing and conducting the research and will furnish periodic progress updates to the NIH throughout the term of the award. After completing the research, the Company must provide the NIH with a formal report describing the work performed and the results of the research.



For funds received under the NIH funding agreement, the Company recognizes a reduction in research and development expenses in an amount equal to the qualifying expenses incurred in each period up to the amount funded by the NIH. Qualifying expenses incurred by the Company in advance of funding by the NIH are recorded in the consolidated balance sheets as other current assets. For the three months ended March 31, 2023, no qualifying expenses have been incurred and nothing has been funded by the NIH. On a cumulative basis as of March 31, 2023, \$1.3 million has been incurred and \$1.3 million has been funded by the NIH.

## 10. Commitments and Contingencies

### Operating Leases

The Company leases office and laboratory space in Redwood City, California, and Boston, Massachusetts.

#### 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 expects to utilize the full allowance for the continued buildout of office and laboratory space at 1000 Bridge Parkway. 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.

#### 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.

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 expected undiscounted cash flows to be received from the sublease as of March 31, 2023 is as follows (in thousands):

	<b>March 31,</b>	
	<b>2023</b>	
2023	\$	531
2024		722
2025		736
2026		438
2027 and thereafter		—
<b>Total</b>	<b>\$</b>	<b>2,427</b>

Further, the Company remains liable for the remaining lease payments under the Master Lease, totaling \$2.2 million, which is included in future minimum lease payments table below.

The future minimum lease payments under all non-cancelable operating lease obligations as of March 31, 2023 were as follows (in thousands):

	<b>March 31, 2023</b>	
2023	\$	3,597
2024		5,005
2025		4,650
2026		3,999
2027 and thereafter		12,059
Total undiscounted lease payments		29,310
Less: imputed interest		(5,813)
Total operating lease liability		23,497
Less: current portion		2,949
Operating lease liability, net of current maturities	\$	20,548

The following table presents the operating lease cost and information related to the operating lease right-of-use assets, net and operating lease liabilities for the quarter ended March 31, 2023 (in thousands):

	<b>March 31, 2023</b>	
<b>Lease Cost</b>		
Operating lease cost	\$	1,141
Short-term lease cost		48
Sublease income		(179)
Total lease cost	\$	1,010
<b>Other Information</b>		
Operating cash flows used for lease liabilities		2,474
Weighted-average remaining lease term - operating leases		6.3
Weighted-average discount rate - operating leases		7%

## 11. Stockholders' Equity

### *Common Stock*

The Company's Certificate of Incorporation, as amended, authorized the Company to issue 150,000,000 shares of common stock, par value \$0.0001 per share, as of March 31, 2023.

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 March 31, 2023, 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:

	<b>March 31, 2023</b>	<b>December 31, 2022</b>
Stock options and restricted stock units available for future grant	3,628,740	2,871,705
Stock options issued and outstanding	8,141,595	6,203,020
Unvested restricted stock units	647,100	197,580
Total common stock reserved	12,417,435	9,272,305

## 12. Stock-based Compensation

### Stock-based Compensation Expense

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

	Three Months Ended March 31,	
	2023	2022
Research and development	\$ 2,207	\$ 1,687
General and administrative	2,558	2,663
<b>Total stock-based compensation</b>	<b>\$ 4,765</b>	<b>\$ 4,350</b>

### Stock Options

A summary of stock option activity for the three months ended March 31, 2023 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)
<b>Outstanding, December 31, 2022</b>	6,203,020	\$ 14.44	8.4	\$ 780
Options granted	2,117,400	\$ 8.06		
Options exercised	(713)	\$ 4.76		
Options forfeited or cancelled	(178,112)	\$ 12.82		
<b>Outstanding, March 31, 2023</b>	<b>8,141,595</b>	<b>\$ 12.82</b>	<b>8.6</b>	<b>\$ 143</b>
Options exercisable, March 31, 2023	2,671,676	\$ 14.15	7.8	\$ 143
Vested and expected to vest, March 31, 2023	8,141,595	\$ 12.82	8.6	\$ 143

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

	Three Months Ended March 31,	
	2023	2022
Fair value of common stock	\$5.76 - \$9.15	\$11.93 - \$19.97
Expected term (years)	6.0 - 6.1	5.8 - 6.1
Volatility	83.25% - 86.19%	77.4% - 77.7%
Risk free rates	3.55% - 4.22%	1.6% - 2.4%
Dividend rate	0.0%	0.0%

### Restricted Stock Units

In October 2021, the Company granted 560,000 Restricted Stock Units (RSUs) with service and performance conditions to certain employees, none of which vested during the three months ended March 31, 2023. Vesting of these awards is contingent on the occurrence of certain milestone events and fulfilment of any remaining service condition. As a result, the related compensation cost is recognized as an expense when achievement of the milestone is considered probable. The expense recognized for these awards is based on the grant date fair value of the Company's common stock multiplied by the number of units granted. The Company recognized \$0.2 million of related expense during the three months ended March 31, 2023.

The summary of RSU activity and related information for the nine months ended March 31, 2023 is set forth below:

	Number of Units Outstanding	Weighted Average Grant Date Fair Value
<b>Outstanding, December 31, 2022</b>	197,580	\$ 7.8
RSUs granted	472,400	\$ 7.8
RSUs vested	(3,205)	\$ 17.2
RSUs forfeited	(19,675)	\$ 7.4
<b>Outstanding, March 31, 2023</b>	<b>647,100</b>	<b>\$ 7.8</b>

### 13. Net Income (Loss) per Share

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

	Three Months Ended March 31,	
	2023	2022
Net income (loss) attributable to common stockholders - basic and diluted	\$ (30,881)	\$ 4,618
Weighted-average shares used in computing net income (loss) per share attributable to common shareholders, basic	42,955,688	39,823,246
Effect of dilutive securities:		
Options to purchase common stock	—	5,376,145
Unvested restricted stock awards	—	538,660
Common stock warrants	—	220,890
Weighted-average shares used in computing net income (loss) per share attributable to common shareholders, diluted	42,955,688	45,958,941
Net income (loss) per share attributable to common stockholders, basic	\$ (0.72)	\$ 0.12
Net income (loss) per share attributable to common stockholders, diluted	\$ (0.72)	\$ 0.10

For the three months ended March 31, 2023, options to purchase 8,141,595 shares of common stock and 647,100 unvested restricted stock awards were excluded from the computation of diluted net loss per share attributable to common stockholders because their effect was antidilutive.

### 14. Income Taxes

The Company recognized no income tax expense during the three months ended March 31, 2023 and 2022. The Company maintains a full valuation allowance against its deferred tax assets due to the Company's history of losses as of March 31, 2023.

### 15. Related Party

As of March 31, 2023, Regeneron owned 883,568 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. For the three months ended March 31, 2023, the Company recorded no revenue from the Regeneron Agreement. See *Note 8* for a discussion of the Regeneron Agreement.

## 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, 2022. 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 allogeneic gamma delta T cell therapies for cancer. We are advancing a pipeline of “off-the-shelf” gamma delta T cells, engineered with chimeric antigen receptors (CARs) and chimeric adaptors (CAbs), to enhance selective tumor targeting and facilitate innate and adaptive anti-tumor immune response for durable activity in patients.

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, ADI-001, a first-in-class allogeneic gamma delta T cell therapy expressing a CAR targeting CD20, is in an ongoing Phase 1 study for the treatment of relapsed or refractory B-cell non-Hodgkin’s lymphoma (NHL). Our pipeline also includes ADI-925, a novel engineered CAbs gamma delta T cell product candidate targeting tumor stress ligands. Our pipeline has several additional internal gamma delta T cell therapy programs in discovery and preclinical development for both hematological malignancies and solid tumors. We expect to continue to develop product candidates in oncology based on the gamma delta T cell platform using either previously validated antigens or those that we identify and target using CAR, CAbs and other technology.

In March 2021, we initiated the first-in-human Phase 1 trial to assess safety and efficacy of ADI-001 in NHL patients. The Phase 1 study for ADI-001 may enroll up to 80 late-stage NHL patients at a number of cancer centers across the United States. The study includes a dose escalation portion followed by dose expansion cohorts to explore the activity of ADI-001 in multiple subtypes of NHL. In April 2022, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation for ADI-001 for NHL. In December 2022, interim results from the trial were presented at the American Society of Hematology (ASH) annual meeting. See “—ADI-001, an Anti-CD20 CAR Gamma Delta T Cell Product Candidate Targeting NHL—Results from Ongoing ADI-001 Phase 1 Trial” section of our Annual Report on Form 10-K for the year ended December 31, 2022 for information regarding the results. Subject to further patient follow-up, we plan to discuss with the FDA during the second quarter of 2023, and later with the EMA, a path forward for a potential pivotal program for ADI-001. We intend to initiate a first potential pivotal study in post-CAR T large B-cell lymphoma (LBCL) patients in the fourth quarter of 2023. We also expect to provide an additional clinical update for the ADI-001 Phase 1 study in the second quarter of 2023.

### Recent Developments

#### *At-the-Market (ATM) Offering*

On March 12, 2021, we entered into a Capital On Demand™ Sales Agreement (Sales Agreement) with JonesTrading Institutional Services LLC (Sales Agent), to provide for the offering, issuance and sale of our common stock from time to time in “at-the-market” offerings (ATM Program). In August 2022, pursuant to the Sales Agreement and subject to the limitations thereof, we sold an aggregate of 2,611,723 shares of common stock at \$17.23 per share resulting in net proceeds to us of \$43.4 million after deducting sales agent commissions and expenses. On November 8, 2022, we filed a prospectus supplement (the New Prospectus) to our registration statement on Form S-3 (File No. 333-254193), which updated and superseded the existing prospectus. The New Prospectus covered the offer and sale of up to \$100.0 million of shares of our common stock from time to time through Sales Agent, acting as our sales agent, under the ATM Program, which includes the \$30.0 million of shares of our common stock not sold pursuant to the existing prospectus and up to an additional \$70.0 million of shares of our common stock.

### ***Third Lease Amendment for Additional Tenant Improvement Allowance***

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 lease agreement, dated as of October 31, 2018, as amended on December 30, 2020, for the premises located at 1000 Bridge Parkway. The Third Amendment increases the tenant improvement allowance as of January 1, 2023 by an additional \$3.0 million, and we expect to utilize the full allowance for the continued buildout of office and laboratory space at 1000 Bridge Parkway. 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. We received the allowance on February 21, 2023.

### ***Letter Agreement with Pacific Western Bank***

On March 13, 2023, we and Pacific Western Bank (PacWest) executed a letter (2023 Letter) agreeing that, notwithstanding the covenants included in the 2022 Loan Amendment (as defined below), until June 30, 2023 (i) we and our subsidiaries will not be required to maintain the lesser of \$200 million or seventy percent (70%) of our combined balances in demand deposit accounts, money market funds and/or insured cash sweep (ICS) accounts with PacWest and (ii) we must maintain our combined balances at PacWest or its affiliates, including Pacific Western Asset Management. At all times following June 30, 2023, we will again be required to comply with the terms of the 2022 Loan Amendment.

Upon executing the 2023 Letter, we wired \$187.2 million from our ICS accounts at PacWest to Pacific Western Asset Management who subsequently invested the funds into money market funds held in custody with U.S. Bank National Association.

### ***Impact of COVID-19 Pandemic***

Global events and macroeconomic conditions such as the COVID-19 pandemic have impacted and may continue to impact our business. Thus far we have not experienced a significant disruption or delay in our operations as it relates to the clinical development of our drug candidates. However, we anticipate that the impact of the COVID-19 pandemic may continue to create difficulties in our clinical trials for a variety of reasons, including future regulations regarding, or the inability or unwillingness of patients to, travel to participate in clinical trials, or to participate in clinical trials that are administered in medical facilities that also treat COVID-19, potential delays in the FDA's review and approval processes and/or shortages of medical supplies that may force medical professionals to focus on non-clinical procedures, including treatment of COVID-19. The duration and ultimate impact of the COVID-19 pandemic on clinical trials generally, and on our trials particularly, is still unknown.

In addition, any resurgence of or spread of new variants of COVID-19 may materially affect us economically. COVID-19 has resulted in, and a similar widespread pandemic in the future could result in, significant disruption of global financial markets, including reduced ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of new COVID-19 variants could materially affect our business. Possible effects may also include absenteeism in our labor workforce, unavailability of products and supplies used in operations, and a decline in value of assets held by us, including property and equipment.

### **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. Our revenues to date have been generated from our License and Collaboration Agreement with Regeneron Pharmaceuticals, Inc. (Regeneron) and the agreement referred to as the "Regeneron Agreement."

We received a non-refundable upfront payment of \$25.0 million from Regeneron upon execution of the Regeneron Agreement on July 29, 2016 and have received an aggregate of \$20.0 million of additional payments for research funding from Regeneron as of March 31, 2023. Our obligations under the Regeneron Agreement were completed during the first quarter of 2022. Regeneron may have to pay us additional amounts in the future consisting of up to an aggregate of \$80.0 million of option exercise fees for a certain number of Interprofessional Collaboration Practices (ICPs). 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 Regeneron potentially has additional options to other Collaboration ICP targets under the Regeneron Agreement. We declined to exercise our option to co-fund the development of ADI-002 with Regeneron, and accordingly, Regeneron must also pay us high single digit royalties as a percentage of net sales for ADI-002 or any other optioned 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 target generated by us through the use of Regeneron's proprietary mice. We must pay Regeneron mid-single to low double digit royalties as a percentage of net sales of Collaboration ICPs to targets for which we have exercised exclusive rights, and low to mid-single digit royalties as

a percentage of net sales of targeting moieties generated from our license to use Regeneron's proprietary mice. Royalties are payable until the longer of the expiration or invalidity of the licensed patent rights or 12 years from first commercial sale.

We used a cost-based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize under the Regeneron Agreement. In applying the cost-based input method of revenue recognition, we used actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. Revenue was recognized based on actual costs incurred as a percentage of total budgeted costs as we completed our performance obligations over the research term. A cost-based input method of revenue recognition requires us to estimate costs to complete our performance obligations, which requires significant judgment to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete our performance obligations is recorded in the period in which changes are identified and amounts can be reasonably estimated.

### ***Operating 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, CDMOs and 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 do not allocate our costs by product candidate, as a significant amount of 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;
- 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 and cash equivalents.

#### *Interest Expense*

Interest expense consists primarily of the non-cash amortization of costs incurred in connection with the Loan Agreement (the Loan Agreement) we entered into with PacWest in April 2020, subsequently amended in October 2021 and December 2022.

#### *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 March 31, 2023 and 2022

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

	Three Months Ended March 31,		Change	% Change
	2023	2022		
Revenue – related party	\$ —	\$ 24,990	\$ (24,990)	(100 %)
Operating expenses				
Research and development	26,756	13,483	13,273	98 %
General and administrative	6,566	6,801	(235)	(3 %)
Total operating expenses	33,322	20,284	13,038	64 %
Income (loss) from operations	(33,322)	4,706	(38,028)	(808 %)
Interest income	2,666	32	2,634	8,231 %
Interest expense	(19)	(18)	(1)	(6 %)
Other expense, net	(206)	(102)	(104)	(102 %)
Income (loss) before income tax benefit	(30,881)	4,618	(35,499)	(769 %)
Income tax provision (benefit)	—	—	—	0 %
Net income (loss)	\$ (30,881)	\$ 4,618	\$ (35,499)	(769 %)

#### Revenue

Revenue decreased by \$25.0 million, or 100%, for the three months ended March 31, 2023 compared to the same period in 2022 resulting from no revenue recognized under the Regeneron Agreement in the current period. Our obligations under the combined performance obligation with Regeneron were completed during the first quarter of 2022, resulting in revenue fully recognized under the agreement as of March 31, 2022. The decrease was also primarily due to the exercise of an option by Regeneron related to ADI-002 which resulted in a \$20.0 million payment received, which was recognized as revenue during the three months ended March 31, 2022.

#### Research and development

	Three Months Ended March 31,	
	2023	2022
Payroll and personnel expenses(1)	\$ 10,662	\$ 6,554
Costs incurred under agreements with consultants, CDMOs, and CROs	8,386	3,384
Lab materials, supplies, and maintenance of equipment used for research and development activities	2,453	1,459
Other research and development expenses(2)	5,255	2,086
Total research and development expenses	\$ 26,756	\$ 13,483

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

(2) 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 increased by \$13.3 million, or 98%, during the three months ended March 31, 2023 compared to the same period in 2022. The increase in research and development expenses was primarily due to a \$5.0 million increase in CDMO and other externally conducted research and development expense and a \$4.1 million increase in payroll and personnel expenses resulting from an increase in overall headcount. There was also a \$3.2 million increase in allocated facility expenses and a \$1.0 million increase in lab supplies and consumable expenses. This was partially offset by a less than \$0.1 million decrease in professional fees.

#### General and administrative

General and administrative expenses decreased by \$0.2 million, or 3%, during the three months ended March 31, 2023 as compared to the same period in 2022. The decrease in general and administrative expenses was primarily due to a \$0.9 million decrease in allocated facility and other costs, a \$0.1 million decrease in stock based compensation and a less than \$0.1 million decrease in professional fees. The decrease was partially offset by a \$0.7 million increase in payroll and personnel expenses, which includes an increase in salaries and benefits of \$0.6 million, contractor fees of \$0.1 million, and

recruiting fees of \$0.1 million. The overall increase in payroll and personnel expenses was the result of increased headcount for the period.

#### *Interest income*

Interest income increased by \$2.6 million, or 8,231%, during the three months ended March 31, 2023 as compared to the same period in 2022, which was primarily due to higher interest rates for the period.

#### *Other expense, net*

Other expense, net increased by \$0.1 million or 102%, during the three months ended March 31, 2023 as compared to the same period in 2022. This was due to an increase in franchise taxes and realized losses related to foreign exchange rates.

### **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 the merger with resTORbio, Inc.

In March 2021, we entered into the Sales Agreement, pursuant to which we could sell, from time to time, at our option, up to an aggregate of \$75.0 million of shares of our common stock, through the Sales Agent. In August 2022, pursuant to this agreement, we sold an aggregate of 2,611,723 shares of common stock at a price per share of \$17.23 to two healthcare-focused institutional investors for net proceeds of approximately \$43.4 million. On November 8, 2022, we filed the New Prospectus, which updated and superseded the existing prospectus. The New Prospectus covers the offer and sale of up to \$100.0 million of shares of our common stock from time to time through JonesTrading Institutional Services LLC, acting as our sales agent, under the ATM Program, which includes the \$30.0 million of shares of our common stock not sold pursuant to the existing prospectus and up to an additional \$70.0 million of shares of our common stock.

As of March 31, 2023, we had cash and cash equivalents of \$231.6 million. We expect that the cash and cash equivalents will be sufficient to fund our forecasted operating expenses, capital expenditure requirements and debt service payments for at least the next twelve months from the issuance of the unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q.

#### *Loan Agreement*

On October 21, 2021, we amended our Loan Agreement with PacWest (as amended, the 2021 Loan Amendment) under which PacWest will provide one or more Term Loans (as defined in the 2021 Loan Amendment), as well as certain Non-Formula Ancillary Services which shall not exceed \$5.5 million in the aggregate. Non-Formula Ancillary Services are defined as automated clearinghouse transactions, corporate credit card services, letters of credit, or other treasury management services. The aggregate sum of the outstanding Term Loans and Non-Formula Ancillary Services shall at no time exceed \$15.0 million, which each Term Loan to be in an amount of not less than \$1.0 million.

On December 2, 2022, we further amended our Loan Agreement with PacWest (the 2022 Loan Amendment) The 2022 Loan Amendment extends the drawdown period for any Term Loan by one year from April 19, 2023 to April 19, 2024. In addition, pursuant to the 2022 Loan Amendment, if we receive at least \$60.0 million from the sale or issuance of our equity securities and/or up-front cash payments from strategic partnerships other than payments from Regeneron on or before September 30, 2023, then the Interest Only End Date (as defined in the 2022 Loan Amendment) will be extended another six months from April 19, 2024 to October 19, 2024. Furthermore, the 2022 Loan Amendment extends the final maturity date of any Term Loan by one year from October 19, 2025 to October 19, 2026, and the maturity date of non-formula ancillary services to November 30, 2023.

On March 13, 2023, we executed the 2023 Letter with PacWest, as defined above.

As of March 31, 2023, we have \$10.6 million available under the Term Loan. Pursuant to the 2021 Loan Amendment, the interest rate for the Term Loans shall be set at an annual rate equal to the greater of (i) 0.25% above the Prime Rate then in effect and (ii) 4.25%.

As of the date of this Quarterly Report on Form 10-Q, we were in compliance with such covenants and had no indebtedness outstanding under the Loan Agreement.

### ***Future Funding Requirements***

We recorded net loss of \$30.9 million for the three months ended March 31, 2023. Prior to this period, we have recorded net losses since inception. As of March 31, 2023, we had an accumulated deficit of \$269.0 million.

As of March 31, 2023, we had cash and cash equivalents of \$231.6 million. We believe that our cash and cash equivalents will be sufficient for us to continue as a going concern for at least 12 months from the issuance date of our unaudited consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. We have based these estimates on assumptions that may prove to be wrong, and we could deplete our available capital resources sooner than we expect. Because of the risks and uncertainties associated with research, development, and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements.

All of our revenue to date has been generated from the Regeneron Agreement, which is a collaboration and license agreement. 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 the COVID-19 pandemic and other 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, cash equivalents, and restricted cash for each of the periods presented below (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Net cash provided by (used in):		
Operating activities	\$ (24,094)	\$ 4,105
Investing activities	(1,915)	(2,632)
Financing activities	(7)	(1,134)
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (26,016)</u>	<u>\$ 339</u>

### **Cash Flows from Operating Activities**

Net cash used in operating activities was \$24.1 million for the three months ended March 31, 2023. Cash used in operating activities consisted of net loss offset by non-cash adjustments of \$6.6 million, and a net increase in assets and liabilities of \$0.2 million. Non-cash items primarily included depreciation and amortization of \$1.3 million, stock-based compensation expense of \$4.8 million, and non-cash lease expense of \$0.6 million. The net change in assets and liabilities was primarily due to a net increase in operating lease liability of \$2.5 million related to the additional tenant improvement allowance as part of the Third Amendment to the lease at 1000 Bridge Parkway, offset by a decrease in accounts payable of \$2.3 million and a decreased in accrued and other current liabilities of \$0.2 million.

Net cash provided by operating activities was \$4.1 million for the three months ended March 31, 2022. Cash provided by operating activities consisted of net income and non-cash adjustments of \$5.4 million, offset by a net decrease in assets and liabilities of \$5.9 million. Non-cash items primarily included depreciation and amortization of \$0.4 million, stock-based compensation expense of \$4.4 million, and non-cash lease expense of \$0.6 million. The net change in assets and liabilities was primarily due to a decrease in deferred revenue of \$4.8 million related to the Regeneron Agreement, a decrease in accrued and other current liabilities of \$1.5 million, and an increase of prepaid expenses and other current assets of \$1.1 million.

### **Cash Flows from Investing Activities**

Net cash used in investing activities was \$1.9 million for the three months ended March 31, 2023, which consisted of purchases of property and equipment of \$1.9 million, primarily related to the construction of our GMP cell processing suite at 1000 Bridge Parkway.

Net cash used in investing activities was \$2.6 million for the three months ended March 31, 2022, which consisted of purchases of property and equipment of \$2.6 million, primarily related to the construction of our new building at 1000 Bridge Parkway.

### **Cash Flows from Financing Activities**

Net cash used in financing activities was less than \$0.1 million for the three months ended March 31, 2023, which was related to cash paid for taxes withheld on the net share settlement of equity awards, offset by net proceeds from the issuance of common stock in connection with the exercise of stock options under our equity plans.

Net cash used in financing activities was \$1.1 million for the three months ended March 31, 2022, which was related to an increase in the cash paid for taxes withheld on the net share settlement of equity awards of \$1.1 million and deferred offering costs paid of \$0.1 million, offset by net proceeds from the issuance of common stock in connection with the exercise of stock options under our equity plans of approximately \$0.1 million.

### **Leases**

We currently lease an office space in Boston, Massachusetts under a non-cancellable operating lease (the Boston Lease), with an expiration date of July 31, 2026. The Boston Lease was amended on April 1, 2019, to relocate into a premises in the same building with additional space. The initial annual base rent for this lease was \$0.6 million and increases 2% annually. On July 19, 2021, we entered into a sublease agreement with the office space in Boston, Massachusetts, or the Sublease Agreement. The term of the Sublease Agreement started on September 1, 2021 and will end on July 30, 2026. The aggregate base rent due to us under the Sublease Agreement is approximately \$3.5 million. Pursuant to the Sublease Agreement, we agreed to transfer certain furniture located in the subleased premises to the sublessee for \$1.00. We remain liable for the lease payments under the Boston Lease.

On October 28, 2018, Adicet Therapeutics executed a non-cancelable lease agreement for an office and laboratory facility at 1000 Bridge Parkway, Redwood City, California (the Redwood City Lease), with an expiration date of February 28, 2030. The initial annual base rent for the Redwood City Lease is an aggregate of \$1.3 million, and such amount will increase 3% annually. On June 16, 2022, Adicet Therapeutics entered into the Second Amendment, which provides for the Expansion Space. Adicet Therapeutics will pay a monthly fee for the Expansion Space increasing annually from approximately \$73,000 to \$78,000 over the thirty-six (36) month term of the Second Amendment. The Second Amendment also provides Adicet Therapeutics with an allowance to construct improvements to the Expansion Space.

On July 21, 2022, we entered a short-term lease agreement with WeWork for a temporary office space located at 200 Berkeley Street, Boston, Massachusetts. The initial lease term commenced on August 1, 2022 and expires on July 31, 2023. The base rent is approximately \$16,000 per month. In April 2023, we signed a new short-term lease agreement with WeWork, increasing the base to approximately \$16,500 per month and extending the lease term until August 31, 2024.

### **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 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 revenue recognition, accruals related to 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, 2022 filed with the SEC on March 15, 2023.

### **Emerging Growth Company and Smaller Reporting**

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the JOBS Act) was enacted. Section 107 of the JOBS Act provides that an emerging growth company (EGC), can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early. We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than \$1.235 billion in annual revenue; (2) the date we qualify as a large accelerated filer, with at least \$700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

We are also a smaller reporting company meaning that the market value of our stock held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Quarterly Report on Form 10-Q and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

### **Recently Issued and Adopted Accounting Pronouncements**

See the section titled “Summary of Significant Accounting Policies” in *Note 2* to our 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 March 31, 2023, we had cash and cash equivalents of \$231.6 million, which consisted of cash 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 and cash equivalents, 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 and cash equivalents. 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 March 31, 2023.

### **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 March 31, 2023, 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. Accordingly, our disclosure controls and procedures provide reasonable assurance, but not absolute 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 March 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 1. Legal Proceedings.**

From time to time, we may be involved in lawsuits, claims, investigations and proceedings, consisting of intellectual property, commercial, employment and other matters which arise in the ordinary course of business. While the outcome of any such proceedings cannot be predicted with certainty, as of March 31, 2023, we were not party to any legal proceedings that we would expect to have a material adverse impact on our financial position, results of operations or cash flow.

**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 March 31, 2023, our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and in other documents that we file with the 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, 2022.*

**Risks Related to Our Business and Industry**

**Risks Related to Operating History**

***We have a limited operating history and face significant challenges and expense 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 a follow-on public offering in December 2021 which raised net proceeds of approximately \$94.2 million from the sale of our common stock as well as an at-the-market offering in August 2022 which raised net proceeds of \$43.4 million. Although we recorded net income of \$4.6 million for the three months ended March 31, 2022, this was primarily due to the exercise of an option by Regeneron under the Regeneron Agreement (as defined below) related to ADI-002 which resulted in a \$20.0 million payment received and recognized as revenue in the three months ended March 31, 2022. For the three months ended March 31, 2023, we recorded net loss of \$30.9 million. As of March 31, 2023, we had an accumulated deficit of \$269.0 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 ADI-001 and ADI-925. 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. 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.

***Our history of recurring losses and anticipated expenditures could raise substantial doubts about our ability to continue as a going concern.***

As of the date of this Quarterly Report on Form 10-Q, we believe that with \$231.6 million in cash and cash equivalents, we are capitalized into the first half of 2025. 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 there is substantial doubt 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.

#### Risks Related to Our Product Candidates

***Our business is highly dependent on the success of ADI-001. If we are unable to obtain regulatory approval for ADI-001 and effectively commercialize ADI-001 for the treatment of patients in our approved indications, our business would be significantly harmed.***

Our business and future success depends on our ability to obtain regulatory approval of, and then successfully commercialize, our most advanced product candidate, ADI-001. ADI-001 is in the early stages of development with an ongoing Phase 1 study to assess the safety and efficacy of ADI-001 in non-Hodgkin's lymphoma (NHL) patients that commenced in March 2021.

Our preclinical results or clinical results to date may not predict results for our planned or ongoing trials or any future studies of ADI-001 or any other allogeneic gamma delta T cell product candidate. 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 ADI-001, 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 ADI-001 is our most advanced product candidate, and because our other product candidates are based on similar technology, if ADI-001 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 cancer treatment that creates 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 patient with certain cancers. Advancing these novel product candidates creates significant challenges for us, including:

- manufacturing our product candidates to our specifications and in a timely manner to support our future clinical trials, and, if approved, commercialization;

- sourcing 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 cancer patients following treatment with our product candidates;
- achieving a side effect profile, including graft versus host disease (GvHD), from our product candidates that makes them 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 U.S. Food and Drug Administration (FDA) and other regulatory authorities have limited experience with development of allogeneic T cell therapies for 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, 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 research and development efforts on our allogeneic gamma delta T cell therapy and our future 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. Approvals by the EMA and FDA for existing autologous chimeric antigen receptor (CAR) T-cell therapies, such as Kymriah® and Yescarta®, may not be indicative of what these regulators may require for approval of our therapies. Also, while we expect reduced variability in our products 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 agency 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. 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. In addition, while we anticipate our focus on gamma delta T cells may lessen the likelihood of GvHD 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, 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. The 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 on management's 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.

#### 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 as products.

In addition, for the ongoing Phase 1 study of ADI-001 and any future 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 our product candidates for approval. 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 Investigational New Drug (IND) applications to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.***

In October 2020, the IND for our lead product candidate, ADI-001, to treat patients with NHL was cleared by the FDA. Our pipeline also includes ADI-925, an engineered chimeric adaptor (CA<sub>d</sub>) T cell product candidate targeting tumor stress ligands. We have five additional internal gamma delta T cell therapy programs in preclinical development and previously

announced our plan to file one new IND every 12-18 months, including one new IND in the second half of 2023. 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 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 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. Moreover, we cannot be assured that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that result in a decision by us, by IRBs, or independent ethics committees or by the FDA, the EMA or other regulatory authorities to suspend or terminate clinical trials, including as a result of a clinical hold. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. The inability to initiate clinical trials any of our product candidates on the timeline currently anticipated 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 suspend or terminate such clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events 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;
- delays in reaching 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 suitable patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or it 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;
- transfer of 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 return for post-treatment follow-up;
- 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; and
- delays in manufacturing, 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.

Our timing of filing on these product candidates is 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 or IND amendment will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

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 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. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. Medicines used at centers to help manage adverse side effects of ADI-001 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, including, without limitation, the impact of the COVID-19 pandemic. 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 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 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.

We intend to conduct a number of clinical trials for product candidates in the fields of cancer in different geographies, all of which have been affected to varying extents by the COVID-19 pandemic. We believe that the COVID-19 pandemic will have an impact on various aspects of our future clinical trials. For example, investigators may not want to take the risk of exposing cancer patients to COVID-19 since the dosing of patients is conducted within an in-patient setting. Other potential impacts of the COVID-19 pandemic on our future various clinical trials include patient dosing and study monitoring, which may be paused or delayed due to changes in policies at various clinical sites, federal, state, local or foreign laws, rules and regulations, including quarantines or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of our clinical trials, interruption or delays in the operations of the government regulators, or other reasons related to the COVID-19 pandemic. It is unknown how long these pauses or disruptions could continue.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our 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 cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and hematopoietic cell transplantation or autologous CAR T-cell therapies, rather than enroll patients in our clinical trial. 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.

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 new 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 NHL 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.

***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 plan to globally develop our product candidates. Accordingly, we expect that it will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, 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 in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- 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 Foreign Corrupt Practices Act 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;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our potential international operations may materially adversely affect our ability to 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 ADI-001 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 will 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 cancers we are targeting, as well as the subset of people with these cancers 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 cancers. 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 ADI-001. Our pipeline also includes ADI-925, an engineered CAd T-cell product candidate targeting tumor stress ligands in the preclinical development stage. In addition, we have five additional internal gamma delta T cell therapy programs in preclinical development and plan to submit one new IND to the FDA every 12-18 months, including one new IND in the second half of

2023. 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 it will be able to successfully advance any of these additional product candidates through the development process.

Even if we receive FDA approval to market additional product candidates for the treatment of cancer, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity 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 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, 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, and the immuno-oncology industry specifically, is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs 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

***We have not yet commenced manufacturing operations at our manufacturing facility and 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 ADI-001. 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 established manufacturing capabilities at our Redwood City facility in the fourth quarter of 2022, 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. 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. While we believe our manufacturing and processing approaches are appropriate to support our clinical product development, 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. We must first receive approval from the FDA prior to licensure to manufacture our product candidates, which we may never obtain. Even if 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 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 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. If we were 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.

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 and 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.

***We will need substantial additional financing to develop our products 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 in the clinical development of our product candidates, including the ongoing Phase 1 clinical trial for ADI-001 and the preclinical development of additional internal gamma delta T cell therapy programs, including ADI-925. 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 March 31, 2023, we believe that with \$231.6 million in cash and cash equivalents, we are capitalized into the first half of 2025. 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. Other than the funding agreement and our loan agreement with Pacific Western Bank (PacWest), 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. Our license agreements may also be terminated if we are unable to meet the payment obligations under the agreements. 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 themselves. 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 or an escalation in conflict between Russia and Ukraine, 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.

***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 transition into operating as a public company, we have rapidly expanded our employee base and expect to continue to add managerial, operational, sales, research and development, marketing, financial and other personnel. 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.

#### Risks Related to Business Disruptions

***Business disruptions could 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, medical epidemics, such as the COVID-19 pandemic, and 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.

***A pandemic, epidemic or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business and operations.***

We are subject to risks related to public health crises such as the COVID-19 pandemic. Our business, financial position, results of operations or cash flows may be affected by a pandemic or epidemic, such as the COVID-19 pandemic, and the resulting volatility and uncertainty it may cause, including as a result of prolonged economic downturn or recession. The COVID-19 pandemic and policies and regulations implemented by governments in response to the COVID-19 pandemic, most of which have been lifted, have had a significant impact, both directly and indirectly, on global businesses and commerce. Such measures have had, and would continue to have, adverse impacts on the United States economy of uncertain severity and duration and may negatively impact our operations and those of third parties on which we rely, including by causing disruptions in the supply of our product candidates and the conduct of current and future clinical trials. In addition, a pandemic or epidemic may affect the operations of the FDA and other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates. A pandemic or epidemic is also likely to directly or indirectly impact the pace of enrollment in our clinical trials as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency, and clinical trial sites may be less willing to enroll patients in clinical trials that may compromise a person's immune system. Such facilities and offices may also be required to focus limited resources on non-clinical trial matters, including treatment of patients impacted by such pandemic or epidemic, and may not be available, in whole or in part, for clinical trial services related to ADI-001 or our other product candidates. Additionally, while the ultimate economic impact, and duration of a pandemic or epidemic are difficult to assess or predict, the impact of such pandemic or epidemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity.

To the extent the COVID-19 pandemic or another pandemic or epidemic may impact our business and financial results, it may also heighten many of the other risks described in this "Risk Factors" section, such as those relating to the timing and completion of our clinical trials and our ability to obtain future financing.

***The current conflict between Russia and Ukraine may increase the likelihood of supply interruptions which could impact our ability to find the materials we need to make our product candidates.***

The ongoing military conflict between Russia and Ukraine may increase the likelihood of supply interruptions and hinder our ability to find the materials we need to make our product candidates. 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 any of these difficulties, our ability to provide our product candidates to patients in preclinical studies or clinical trials, such as our clinical trial of ADI-001 in NHL patients, could be delayed or suspended. Any delay or interruption in the supply of trial materials 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.

***Inadequate funding for the FDA and other government agencies, or disruptions in their staffing levels related to the COVID-19 global pandemic, 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.***

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, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. Should FDA determine that an inspection is necessary for approval of a marketing application and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, FDA has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our

regulatory submissions, which could have a material adverse effect on our business, including our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

### Risks Related to Healthcare Regulation

***Our relationships with customers, physicians including clinical investigators, clinical research organizations 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 United States Healthcare Laws and Compliance Requirements*” in our Annual Report on Form 10-K for the year ended December 31, 2022.

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 ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, 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 requires covered businesses to, among other things, provide disclosures 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 California Consumer Privacy Act (CCPA), and the Virginia Consumer Data Protection Act became effective on January 1, 2023 and comprehensive privacy laws will become effective in Colorado, Connecticut and Utah in 2023 as well as in Iowa in 2025. Further, numerous other states have proposed similar privacy laws. We believe that further increased

regulation in additional jurisdictions is likely in the area of data privacy. Any of the foregoing may have a material adverse effect on our ability to provide services to patients and, in turn, our results of operations.

The collection and use of personal health data in the European Economic Area (EEA) is governed by the General Data Protection Regulation, or 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 data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for “high risk” processing, limitations on retention of personal data, mandatory data breach notification and “privacy by design” requirements, and creates direct obligations on service providers acting as data 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.

In addition, further to the United Kingdom’s (UK’s) exit from the European Union (EU) on January 31, 2020, the GDPR ceased to apply in the United Kingdom at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the United Kingdom’s European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the United Kingdom’s data protection regime, which is independent from but aligned to the European Union’s data protection regime. Although the 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. The UK government has announced plans to reform the data protection legal framework in the UK in its Data Reform Bill but those have been put on hold. 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 European Union’s GDPR, the European Commission has now 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. 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. On June 4, 2021, the EC issued new 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 new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive. 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. Following a ruling from the Court of Justice of the EU, in *Data Protection Commissioner v Facebook Ireland Limited and Maximillian Schrems*, Case C-311/18 (“Schrems II”), 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. We will be 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 or UK GDPR and the related national data protection laws of the EEA Member States may result in fines up to €20 million or 4% of a company’s global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR and UK GDPR grant 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 and UK 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 jurisdictions outside of Europe are also considering and/or enacting 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.

### Risks Related to Our Financial Position

#### ***Raising funds through lending arrangements may restrict our operations or produce other adverse results.***

Our current Loan and Security Agreement with PacWest, as further amended on July 8, 2020, September 14, 2020, September 15, 2020, October 21, 2022 and December 2, 2022 (the Loan Agreement), sets the interest rate of the term loans under the Loan Agreement at the greater of (i) 0.25% above the Prime Rate then in effect and (ii) 4.25%. The Loan Agreement contains a variety of affirmative and negative covenants, including required financial reporting, requirements to maintain certain balances at PacWest, limitations on certain dispositions of assets, limitations on the incurrence of additional debt and other requirements. To secure our performance of our obligations under this Loan Agreement, we granted a security interest in substantially all of our assets, other than certain intellectual property assets, to PacWest and issued a warrant to purchase our capital stock.

On March 13, 2023, we executed a letter agreeing that, notwithstanding the covenants included in the Fifth Amendment to the Loan Agreement, dated as of December 2, 2022 (the 2022 Loan Amendment), until June 30, 2023 (i) we and our subsidiaries will not be required to maintain the lesser of \$200 million or seventy percent (70%) of our combined balances in demand deposit accounts, money market funds and/or insured cash sweep (ICS) accounts with PacWest and (ii) we must maintain our combined balances at PacWest or its affiliates, including Pacific Western Asset Management (the Letter). At all times following June 30, 2023, we will again be required to comply with the terms of the 2022 Loan Amendment. Upon executing the Letter, we wired \$187.2 million from our ICS accounts at PacWest to Pacific Western Asset Management who subsequently invested the funds into money market funds held in custody with U.S. Bank National Association.

Our failure to comply with the covenants in the Loan Agreement, including as a result of changing the position of certain of our accounts, failure to transfer funds back to PacWest at expiration of the Letter, the occurrence of a material impairment in our prospect of repayment operations, business or financial condition, our ability to repay the loan, or in the value, perfection or priority of PacWest's lien on our assets, as determined by PacWest, or the occurrence of certain other specified events could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt, potential foreclosure on our assets and other adverse results. Additionally, we are bound by certain negative covenants setting forth actions that are not permitted to be taken during the term of the Loan Agreement without consent of PacWest, including, without limitation, incurring certain additional indebtedness, making certain asset dispositions, entering into certain mergers, acquisitions or other business combination transactions or incurring any non-permitted lien or other encumbrance on our assets. The foregoing prohibitions and constraints on our operations could result in our inability to: (a) acquire promising intellectual property or other assets on desired timelines or terms; (b) reduce costs by disposing of assets or business segments no longer deemed advantageous to retain; (c) reallocate certain of our cash deposits and money market accounts depending on various global banking events; (d) stimulate further corporate growth or development through the assumption of additional debt; or (e) enter into other arrangements that necessitate the imposition of a lien on corporate assets. Moreover, if the conditions set forth in the consent provided by PacWest are not satisfied, or if we do not comply with the terms of the Letter, we would effectively need to terminate the Loan Agreement and repay any outstanding loan funds or refinance the facility with another lender. As of the date of this Quarterly Report on Form 10-Q, no amounts have been drawn under the Loan Agreement.

#### ***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, including PacWest or its affiliates, 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.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our customers or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer or supplier bankruptcy or insolvency, or the failure of any customer to make payments when due, or any breach or default by a customer or supplier, or the loss of any significant supplier relationships, could result in material losses to us and may material adverse impacts on our business.



***Failure 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. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements, or 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 an emerging growth company (EGC) or a smaller reporting company (SRC), our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We will remain an EGC until the earliest to occur of: (1) the last day of the fiscal year in which we have more than \$1.235 billion in annual revenue; (2) the date we qualify as a large accelerated filer, with at least \$700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; or (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering, which would be December 31, 2023.

We will qualify as a SRC if the market value of our common stock held by non-affiliates is less than \$250 million (or \$700 million if our annual revenue is less than \$100 million) as of June 30 in any given year. 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.

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.

**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, 2022, we had federal net operating loss carryforwards of approximately \$271.2 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.

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

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. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made and changes are likely to continue to occur in the future.

Additional changes to U.S. federal income tax law are currently being contemplated, and future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be

enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. 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 December 31, 2022, 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 and discovery agreement with Twist Bioscience Corporation (Twist), that we believe can provide us with additional capabilities beneficial to our business. 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. We may receive additional technologies, expertise and funding under other collaborations in the future. Our existing therapeutic collaborations, and any future collaborations we enter into, may pose a number of 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 our 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 therapeutic 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 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 the Regeneron collaboration described above, for some of our programs, 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. For example, in April 2020, Johnson & Johnson entered into a collaboration agreement with Fate Therapeutics, a company that is also using allogeneic T cell technologies, for up to four CAR Natural Killer (NK) and CAR T-cell therapies. 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.***

During the five-year period following the effective date of the Regeneron Agreement, with certain limited exceptions, we may not directly or indirectly research, develop, manufacture or commercialize a gamma delta immune cell product (ICP) or grant a license to do the foregoing, except pursuant to the terms of the Regeneron Agreement. Both parties also have obligations not to research, develop, manufacture or commercialize an 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 oncology. 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 exclusivity obligations under the Regeneron Agreement expired on July 29, 2021. Prior to this expiration date, our ability to advance any gamma delta immune cell therapeutics outside of the scope of the research plan agreed on with Regeneron was limited. 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 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 will rely heavily on these third parties over the course of our 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 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.***

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 after receipt of FDA questions, if any;
- 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, the Drug Enforcement Administration 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.***

Our internal computer systems and the systems of our CROs, contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Additionally, as a result of the COVID-19 pandemic, we have transitioned certain of our workforce to a remote working model. 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 cyberattacks and privacy incidents. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material 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.

***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;
- 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 cancer. We may also request regulatory approval of future product candidates by target, regardless of cancer type or origin, which the FDA may have difficulty accepting if our clinical trials only involved cancers of certain origins. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in obtaining regulatory approvals, including but not limited to:

- obtaining regulatory authorization to begin a trial, if applicable;
- redesigning our study protocols and need to 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 having patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or return for post-treatment follow-up;
- difficulty in having patients complete a trial or 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, for the completion in preclinical and clinical studies;
- 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, such as the COVID-19 pandemic.



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 will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

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 sooner than anticipated.***

The Biologics Price Competition and Innovation Act (BPCIA) was enacted as part of the Affordable Care Act to establish 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. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that are approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

***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 those responsible for regulation of existing cell therapy products.

Complex regulatory environments 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 (CAT) was established within the EMA in accordance with Regulation (EC) 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 or drug is for the sponsor to provide dispositive data from two well-controlled, Phase 3 clinical studies of the relevant biologic or drug 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, we do not have any agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a BLA. In addition, the FDA may only allow us to evaluate patients that have failed or who are ineligible for autologous therapy, which are extremely difficult patients to treat and patients with advanced and aggressive cancer, and our product candidates may fail to improve outcomes for such patients.

The FDA may grant accelerated approval for our product candidates and, 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, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. In addition, 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 show that our product candidate is superior 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;
- 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 commercial manufacturing facility and may not approve our facility; 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 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.

***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. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are 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 also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. 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.

Additionally, on June 23, 2016, the UK held a referendum in which a majority of voters approved an exit from the EU, or Brexit, and the UK formally left the EU on January 31, 2020. There was a transition period during which EU pharmaceutical laws continued to apply to the UK, which expired on December 31, 2020. However, the EU and the UK have concluded a trade and cooperation agreement (TCA) which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland). The regulatory regime in Great Britain therefore currently aligns in the most part with EU regulations, however it is possible that

these regimes will diverge in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. For example, the new Clinical Trials Regulation, which became effective in the EU on January 31, 2022 and provides for a streamlined clinical trial application and assessment procedure covering multiple EU Member States, has not been implemented into UK law, and a separate application will need to be submitted for clinical trial authorization in the UK. The separate, and potentially diverging, regulatory regimes between Great Britain and the EU may increase our regulatory burden of applying for and obtaining authorization in Great Britain and the EU.

***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, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping 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 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. 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, we will 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, 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;
- the FDA placing a product on a list of discontinued products, which would revoke the product's ability to be marketed, if the sponsor of the approved biologic fails to provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a biologic; 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 a potential cancer treatment 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 in the large bone marrow transplant centers 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 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, 2022.

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, 2022.

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. For example, in August 2022, the Inflation Reduction Act of 2022 (the IRA) was signed into law. The IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to \$2,000 starting in 2025; 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 the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The effects of the IRA on our business and the healthcare industry in general is not yet known.

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.

On July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede generic drug and biosimilar competition.



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 drug 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.

### **Risks Related to Our 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. 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 parties 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 ADI-001, ADI-925 and ADI-002, 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 ADI-001, ADI-925, ADI-002 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

***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 shares began trading on The Nasdaq Global Select Market on January 26, 2018. Given the limited trading history of our common stock, 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.

***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 ADI-001 in NHL;
- the timing and results of preclinical studies of ADI-925 in NHL;
- 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;
- 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.

***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 owned, in the aggregate, approximately 48.6% of our outstanding voting common 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, not only in light of the COVID-19 pandemic and the potential global recession resulting therefrom, but also due to recent global tensions and unexpected shifts in political, legislative and regulatory conditions concerning, among other matters, international trade and taxation, and that an uneven recovery or a renewed global downturn 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 third amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the 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 amended and restated 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 director, officer or other employee of ours to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or the restated 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 an EGC and the reduced disclosure requirements applicable to EGCs may make our common stock less attractive to investors.***

We are an EGC, and, for as long as we continue to be an EGC, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies." We will remain an EGC until the earliest to occur of: (1) the last day of the fiscal year in which we have more than \$1.235 billion in annual revenue; (2) the date we qualify as a large accelerated filer, with at least \$700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering, which would be December 31, 2023. For as long as we remain an "emerging growth company," we expect to avail ourselves of the exemptions from various reporting requirements applicable to other public companies but not to EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (Section 404).

Assuming we do not surpass one of the thresholds in clauses (1) through (3), our status as an EGC will end on December 31, 2023, which will be the last day of the fiscal year ending after the fifth anniversary of our initial public offering. As such, we will be subject to the disclosure requirements applicable to other public companies that were not applicable to us as an EGC. These requirements include:

- compliance with the auditor attestation requirements of Section 404;
- compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- full disclosure obligations regarding executive compensation; and
- compliance with the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Additionally, we expect that our loss of EGC status will require additional attention from management and will result in increased costs to us, which could include higher legal fees, accounting fees and fees associated with investor relations activities, among others.

***We are also a 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 until our public float exceeds \$250 million or our annual revenues exceed \$100 million with a public float greater than \$700 million.

***We have broad discretion over the use of our cash and cash equivalents and may not use them effectively.***

Our management has broad discretion to use our cash and cash equivalents 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 ourselves 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 12, 2021, we filed a registration statement on Form S-3 (File No. 333-254193) with the SEC, which was declared effective on March 30, 2021 (2021 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. We also simultaneously entered into a Capital On Demand™ Sales Agreement (Sales Agreement) with JonesTrading Institutional Services LLC (Sales Agent), to provide for the offering, issuance and sale of up to an aggregate amount of \$75.0 million of shares of our common stock from time to time in “at-the-market” offerings under the 2021 Shelf Registration Statement and filed a prospectus with the 2021 Shelf Registration

Statement for the offer and sale of up to an aggregate amount of \$75.0 million of shares of our common stock from time to time through the Sales Agent. On November 8 2022, we 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 our common stock from time to time through the Sales Agent, which includes the \$30.0 million of shares of our common stock not sold under the original prospectus and up to an additional \$70.0 million of shares of our common stock. We will pay to the Sales Agent cash commissions of 3.0% of the aggregate gross proceeds of sales of common stock under the Sales Agreement. Sales of common stock, debt securities or other equity securities by us may represent a significant percentage of our common stock currently outstanding. On March 15, 2022, we filed a registration statement on Form S-3 (File No. 333-263587) with the SEC, which was amended by the Amendment No. 1 to the Registration Statement on Form S-3, as filed with the SEC on March 16, 2022, declared effective on May 9, 2022 (2022 Shelf Registration Statement, together with the 2021 Shelf Registration Statement, the Shelf Registration Statements), 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 Shelf Registration Statements 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 and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

Not applicable.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

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

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
3.1	<a href="#"><u>Third Amended and Restated Certificate of Incorporation of the Registrant (as currently in effect) (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on January 30, 2018).</u></a>
3.2	<a href="#"><u>Certificate of Amendment of Third Amended and Restated Certificate of Incorporation of resTORbio, Inc. related to the Reverse Stock Split, dated September 15, 2020 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 16, 2020).</u></a>
3.3	<a href="#"><u>Certificate of Amendment of Third Amended and Restated Certificate of Incorporation of resTORbio, Inc. related to the Name Change, dated September 15, 2020 (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 September 16, 2020).</u></a>
3.4	<a href="#"><u>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).</u></a>
10.1	<a href="#"><u>Third Amendment to Lease, dated as of January 9, 2023, by and between Adicet Therapeutics, Inc. as Tenant, and Westport Office Park, LLC as Landlord (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 15, 2023).</u></a>
10.2*	<a href="#"><u>Amended and Restated Non-Employee Director Compensation Policy</u></a>
31.1*	<a href="#"><u>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.</u></a>
31.2*	<a href="#"><u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.</u></a>
32.1**	<a href="#"><u>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.</u></a>
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF\* Inline XBRL Taxonomy Extension Definition Linkbase Document  
101.LAB\* Inline XBRL Taxonomy Extension Label Linkbase Document  
101.PRE\* Inline XBRL Taxonomy Extension Presentation Linkbase Document  
104\* Cover Page Interactive Data File

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\* Filed herewith.

\*\* 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: May 9, 2023

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

Date: May 9, 2023

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

## ADICET BIO, INC.

### AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The purpose of this Amended and Restated Non-Employee Director Compensation Policy (the “Policy”) of Adicet Bio, Inc. (the “Company”), is to provide a total compensation package that enables the Company to attract and retain, on a long-term basis, high-caliber directors who are not employees or officers of the Company or its subsidiaries. In furtherance of the purpose stated above, all non-employee directors shall be paid compensation for services provided to the Company as set forth below:

#### **Cash Retainers**

Annual Retainer for Board Membership: \$40,000 for general availability and participation in meetings and conference calls of our Board of Directors (the “Board”). No additional compensation will be paid for attending individual meetings of the Board.

Additional Annual Retainer for Non-Executive Chair of the Board: \$30,000

Additional Annual Retainers for Committee Membership:

Audit Committee Chair: \$15,000

Audit Committee member: \$7,500

Compensation Committee Chair: \$10,000

Compensation Committee member: \$5,000

Nominating and Corporate Governance Committee Chair: \$8,000

Nominating and Corporate Governance Committee member: \$4,000

No additional compensation for attending individual committee meetings. All cash retainers will be paid quarterly, in arrears, or upon the earlier resignation or removal of the non-employee directors, pro-rated based on the number of actual days served by the director during such calendar quarter. Chair and committee member retainers are in addition to retainers for members of the Board.

#### **Equity Retainers**

Initial Award: An initial, one-time equity award (the “Initial Award”) of 70,200 options to each new non-employee director upon his or her election to the Board, which shall vest in thirty-six (36) equal monthly beginning on the date of grant, however, that all vesting shall cease if the director resigns from the Board or otherwise ceases to serve as a director of the Company. This Initial Award applies only to non-employee directors who are first elected to the Board subsequent to the Company’s initial public offering. If the Initial Award is in the form of a stock



option, such stock option shall have a per share exercise price equal to the Fair Market Value (as defined in the Company's 2018 Stock Option and Incentive Plan) of the Company's common stock on the date of grant.

**Annual Award:** On each date of the Company's Annual Meeting of Stockholders following the completion of the Company's initial public offering (the "Annual Meeting"), each continuing non-employee member of the Board, other than a director receiving an Initial Award, will receive an annual equity award (the "Annual Award") of 26,400 options and 5,900 restricted stock units, which shall vest in full upon the earlier to occur of the first anniversary of the date of grant or the date of the next Annual Meeting; provided, however, that all vesting shall cease if the director resigns from the Board or otherwise ceases to serve as a director, unless the Board determines that the circumstances warrant continuation of vesting. If the Annual Award is in the form of a stock option, such stock option shall have a per share exercise price equal to the Fair Market Value (as defined in the Company's 2018 Stock Option and Incentive Plan) of the Company's common stock on the date of grant.

### **Expenses**

The Company will reimburse all reasonable out-of-pocket expenses incurred by non-employee directors in attending meetings of the Board or any Committee.

Adopted by the Board on December 21, 2017, as amended by the Board on April 30, 2021 and subsequently on January 27, 2022 and January 24, 2023.

**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

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

Date: May 9, 2023

**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

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**Nick Harvey**  
**Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**

Date: May 9, 2023

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**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 March 31, 2023 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

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

Date: May 9, 2023

/s/ Nick Harvey

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**Nick Harvey**  
**Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**

Date: May 9, 2023

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