

**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, 2022

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 No. 001-38359

Adicet Bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

200 Clarendon Street, Floor 6
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
Common Stock, par value \$0.0001 per share

Trading Symbol(s)
ACET

Name of each exchange on which registered
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
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

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

As of May 9, 2022, the registrant had 40,004,357 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 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 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 do not currently operate our own 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.
- 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. 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.
- 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 agreement 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 U.S. Food and Drug Administration 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.
- 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.

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:

- 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 the availability, timing and announcement of data from our Phase 1 clinical trial;
- the anticipated timing of our submission of Investigational New Drug (IND) applications or equivalent regulatory filings and initiation of future clinical trials, including the timing of the anticipated results;
- the impact of the ongoing 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;
- 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 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, cash equivalents and marketable securities;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to maintain effective internal control over financial reporting;
- the impact of government laws and regulations; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

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

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

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

Item 1. Consolidated Financial Statements.

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 277,883	\$ 277,544
Accounts receivable—related party	—	185
Prepaid expenses and other current assets	3,649	4,709
Total current assets	281,532	282,438
Property and equipment, net	17,736	14,643
Operating lease right-of-use asset	19,713	20,358
Goodwill	19,462	19,462
Restricted cash	150	150
Other non-current assets	1,858	1,887
Total assets	<u>\$ 340,451</u>	<u>\$ 338,938</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,465	\$ 3,263
Contract liabilities — related party, current	—	4,805
Accrued and other current liabilities	5,203	6,682
Operating lease liability	1,733	1,567
Total current liabilities	10,401	16,317
Operating lease liability, net of current portion	18,851	19,377
Other non-current liabilities	115	115
Total liabilities	29,367	35,809
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized as of March 31, 2022 and December 31, 2021, respectively; none issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	—	—
Common stock, \$0.0001 par value, 150,000,000 shares authorized as of March 31, 2022 and December 31, 2021, respectively; 39,885,816 and 39,736,914 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	4	4
Additional paid-in capital	474,786	471,449
Accumulated deficit	(163,706)	(168,324)
Accumulated other comprehensive income	—	—
Total stockholders' equity	311,084	303,129
Total liabilities and stockholders' equity	<u>\$ 340,451</u>	<u>\$ 338,938</u>

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)

	Three Months Ended March 31,	
	2022	2021
Revenue—related party	\$ 24,990	\$ (3,981)
Operating expenses:		
Research and development	13,483	11,743
General and administrative	6,801	5,630
Total operating expenses	<u>20,284</u>	<u>17,373</u>
Income (loss) from operations	4,706	(21,354)
Interest income	32	41
Interest expense	(18)	(50)
Other expense, net	(102)	(4)
Income (loss) before income tax benefit	4,618	(21,367)
Income tax benefit	—	(48)
Net income (loss)	<u>\$ 4,618</u>	<u>\$ (21,319)</u>
Net income (loss) per share attributable to common stockholders, basic	<u>\$ 0.12</u>	<u>\$ (0.82)</u>
Net income (loss) per share attributable to common stockholders, diluted	<u>\$ 0.10</u>	<u>\$ (0.82)</u>
Weighted-average common shares used in computing net income (loss) per share attributable to common stockholders, basic	<u>39,823,246</u>	<u>26,099,954</u>
Weighted-average common shares used in computing net income (loss) per share attributable to common stockholders, diluted	<u>45,958,941</u>	<u>26,099,954</u>
Other comprehensive loss:		
Unrealized loss gain on marketable debt securities, net of tax	—	(22)
Total other comprehensive loss	—	(22)
Comprehensive income (loss)	<u>\$ 4,618</u>	<u>\$ (21,341)</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 Shareholders' Equity
	Shares	Amount			
Balance at December 31, 2021	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 loss	—	—	—	4,618	4,618
Balance at March 31, 2022	<u>39,885,816</u>	<u>\$ 4</u>	<u>\$ 474,786</u>	<u>\$ (163,706)</u>	<u>\$ 311,084</u>

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

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' (Deficit)
	Shares	Amount				
Balance at December 31, 2020	19,677,249	\$ 2	\$ 216,126	\$ (106,325)	\$ 24	\$ 109,827
Issuance of common stock upon exercise of stock options	393,991	—	976	—	—	976
Issuance of common stock related to financing	11,729,353	1	143,753	—	—	143,754
Exercise of warrant	1,806	—	—	—	—	—
Stock-based compensation expense	—	—	3,043	—	—	3,043
Net loss	—	—	—	(21,319)	—	(21,319)
Other comprehensive loss	—	—	—	—	(22)	(22)
Balance at March 31, 2021	<u>31,802,399</u>	<u>\$ 3</u>	<u>\$ 363,898</u>	<u>\$ (127,644)</u>	<u>\$ 2</u>	<u>\$ 236,259</u>

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

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

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities		
Net income (loss)	\$ 4,618	\$ (21,319)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization expense	352	326
Noncash lease expense	645	686
Stock-based compensation expense	4,350	3,043
Net amortization of premiums and accretion discounts on investments	—	9
Loss on disposal of property, plant, and equipment	18	—
Amortization of deferred debt issuance costs	18	184
Impairment of in-process research and development	—	460
Reduction to revenue	—	3,981
Remeasurement of contingent consideration liability	—	(380)
Changes in operating assets and liabilities:		
Accounts receivable - related party	185	—
Prepaid expenses and other current assets	1,077	36
Other non-current assets	117	(377)
Accounts payable	(612)	196
Contract liabilities — related party	(4,805)	—
Operating lease liability	(361)	(438)
Accrued and other current and non-current liabilities	(1,497)	(1,553)
Net cash provided by (used in) operating activities	<u>4,105</u>	<u>(15,146)</u>
Cash flows from investing activities		
Proceeds from sales of marketable debt securities	—	7,500
Proceeds from maturities of marketable debt securities	—	1,000
Purchases of property and equipment	(2,632)	(658)
Net cash provided by (used in) investing activities	<u>(2,632)</u>	<u>7,842</u>
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	—	143,754
Proceeds from exercise of stock options	94	976
Taxes withheld and paid related to net share settlement of equity awards	(1,106)	—
Deferred issuance costs	(122)	157
Net cash provided by (used in) financing activities	<u>(1,134)</u>	<u>144,887</u>
Net change in cash, cash equivalents and restricted cash	339	137,583
Cash, cash equivalents and restricted cash, at the beginning of period	277,694	88,857
Cash, cash equivalents and restricted cash, at the end of period	<u>\$ 278,033</u>	<u>\$ 226,440</u>
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	\$ 277,883	\$ 221,667
Restricted cash	150	4,773
Cash, cash equivalents and restricted cash	<u>\$ 278,033</u>	<u>\$ 226,440</u>
Supplemental cash flow information		
Cash received from tax refund	\$ —	\$ 158
Supplemental disclosures of noncash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 1,481	\$ 67
Adjustment to goodwill	\$ —	\$ 56

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 T cell receptor-like antibodies to enhance selective tumor targeting, facilitate innate and adaptive anti-tumor immune response, and improve persistence 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 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 another office in Menlo Park, 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 \$163.7 million as of March 31, 2022. The Company has historically financed its operations primarily through a collaboration and licensing arrangement, through the 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.

In February 2021, the Company completed an underwritten public offering of 10,575,513 shares of its common stock at a public offering price of \$13.00 per share. The Company received aggregate gross proceeds from the offering, before deducting underwriting discounts and commissions and offering expenses of approximately \$137.5 million. In connection with the offering, the Company also entered into a stock purchase agreement with certain existing investors for \$15.0 million of shares of the Company's common stock at a price per share equal to the public offering price, with an initial closing for certain investors held simultaneously with the closing of the offering and a subsequent closing for certain additional investors.

In December 2021, the Company closed an underwritten public offering of 7,187,500 shares of its common stock at a public offering price of \$14.00 per share. The Company received net proceeds from the offering, after deducting underwriting discounts and commissions and offering expenses, of approximately \$94.2 million.

The Company expects that its cash and cash equivalents, including the gross proceeds it received in February 2021 and December 2021 from its underwritten public offerings and the proceeds received from a stock purchase agreement with certain existing investors, 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 is 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 manufacturing organizations (CMOs), 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, 2021. There have been no material changes to the significant accounting policies during the three months ended March 31, 2022.

Unaudited Interim Financial Information

The accompanying unaudited consolidated financial statements as of March 31, 2022 and for the three months ended March 31, 2022 and 2021, have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (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, 2021. 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, 2022 and consolidated results of operations for the three months ended March 31, 2022 and 2021 and consolidated cash flows for the three months ended March 31, 2022 and 2021 have been made. The results of operations for the three months ended March 31, 2022 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2022.

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 two financial institutions 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.

The Company has one customer, Regeneron, which represents all of the Company's revenue for the three months ended March 31, 2022 and 2021 (see Note 8).

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.

The current COVID-19 (coronavirus) pandemic, which is impacting worldwide economic activity, poses the risk that the Company or its employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities. The extent to which the coronavirus impacts the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. COVID-19 may impact the timing of regulatory review and clearance of investigational new drugs (INDs) for clinical trials, the enrollment of any clinical trials that are allowed to proceed, the availability of clinical trial materials and regulatory approval and commercialization of our product candidates. COVID-19 may also impact the Company's ability to access capital, which could negatively impact short-term and long-term liquidity.

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 July 2021, FASB issued ASU No. 2021-05, *Lease (Topic 842), Lessors - Certain Leases with Variable Lease Payments* (ASU 2021-05). ASU 2021-05 amends the lease classification requirements for lessors when classifying and accounting for a lease with variable lease payments that do not depend on a reference rate index or a rate. The update provides criteria, that if met, the lease would be classified and accounted for as an operating lease. ASU 2021-05 is effective for reporting periods beginning after December 15, 2021, with early adoption permitted. The Company adopted ASU 2021-05 in the first quarter of 2022. The impact on its consolidated financial statements and related disclosures was not material.

Accounting Pronouncements Not Yet Adopted

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 plans to adopt the provisions of ASU 2016-13 effective January 1, 2023 and is currently evaluating the impact the adoption of this ASU will have on its 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 plans to adopt the provisions of ASU 2017-04 effective January 1, 2023 and is currently evaluating the impact the adoption of this ASU will have on its consolidated financial statements and related disclosures.

3. Goodwill and Other Intangible Assets

On September 15, 2020, Former Adicet completed its merger with resTORbio. The merger was accounted for as a business combination which requires that assets acquired, and liabilities assumed be recognized at their fair value as of the acquisition date. While the Company uses its best estimates and assumptions as part of the purchase price allocation process to value the assets acquired and liabilities assumed on the acquisition date, its estimates and assumptions are subject to refinement. Fair value estimates are based on a complex series of judgments about future events and uncertainties and rely heavily on estimates and assumptions. The judgments used to determine the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives, can materially impact the Company's results of operations.

As part of the transaction the Company recognized goodwill of \$19.5 million, which is not tax deductible and represents the excess of the consideration paid over the fair value of assets acquired and liabilities assumed. Goodwill is mainly attributable to the enhanced value of the combined company.

The fair value of acquired in-process research and development (IPR&D) is related to the research and development of RTB101 for a COVID-19 related indication. The RTB101 compound IPR&D project was valued using an income approach, specifically a projected discounted cash flow method, adjusted for the probability of technical success (PTS). The projected discounted cash flow models used to estimate the Company's IPR&D reflect significant assumptions regarding the estimates a market participant would make in order to evaluate a drug development asset, including the following:

- Estimates of potential cash flows to be generated by the project and resulting asset, which was developed utilizing estimates of total patient population, market penetration rates, demand risk adjustment factors, and product pricing;
- Estimates regarding the timing of and the expected costs of goods sold, research and development expenses, selling, general and administrative expenses to advance the clinical programs to commercialization, cash flow adjustments and partner profit split;
- The projected cash flows were then adjusted using PTS factors that were selected considering both the current state of clinical development and the nature of the proposed indication, (i.e., respiratory therapeutics); and
- Finally, the resulting probability adjusted cash flows were discounted to a present value using a risk-adjusted discount rate, developed considering the market risk present in the forecast and the size of the asset.

This IPR&D intangible asset is not amortized, but rather is reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed, abandoned, or transferred to a third party. On July 27, 2021, the Company sent Novartis a termination notice. Termination will automatically take effect as of 60 days from the date of delivery of the termination notice to Novartis, but in no event later than October 1, 2021 without any further notice or action required of either Novartis or the Company. Upon the review of impairment of IPR&D during the second quarter of 2021, the Company concluded that the IPR&D was fully impaired and recorded an impairment charge within research and development expenses in the consolidated statement of operations and comprehensive loss for the remaining balance of the IPR&D intangible asset as of June 30, 2021. The Company recognized IPR&D impairment charges of \$2.3 million, \$0.5 million, and \$0.7 million for the quarters ended as of December 31, 2020, March 31, 2021, and June 30, 2021.

In connection with the merger, the Company entered into a Contingent Value Rights Agreement (the CVR Agreement). The contingent consideration for the contingent value right (CVR) was valued using an income approach, leveraging the probability adjusted discounted cash flow used in the valuation of the IPR&D and then deducting the administrative fee to be retained by the combined company and other permitted deductions in order to arrive at the net cash expected to be paid out to the CVR holders. The probability adjusted cash flow includes significant estimates and assumptions pertaining to commercialization events and cash consideration received by the Company for the grant of rights to commercialize RTB101 during the term of the CVR Agreement. These cash flows were then discounted to present value using the same discount rate applied in the valuation of the IPR&D. For additional background on the CVR Agreement and IPR&D, see to Note 3 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

The following tables present changes in the Company's IPR&D and CVR since the merger (in thousands):

	Acquisition Date Fair value as of September 15, 2020	Change in Fair value	As of December 31, 2020	Change in Fair value	As of December 31, 2021
In-process research and development	\$ 3,490	\$ (2,300)	\$ 1,190	\$ (1,190)	\$ —
Contingent Value Rights	\$ 2,880	\$ (1,900)	\$ 980	\$ (980)	\$ —

4. 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, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (1) (2)	\$ 147,075	\$ —	\$ —	\$ 147,075
Total fair value of assets	\$ 147,075	\$ —	\$ —	\$ 147,075
	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (1) (2)	\$ 147,071	\$ —	\$ —	\$ 147,071
Total fair value of assets	\$ 147,071	\$ —	\$ —	\$ 147,071

- (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.

5. Prepaid Expenses and Other Current Assets

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

	March 31, 2022	December 31, 2021
Prepaid insurance	\$ 1,414	\$ 1,021
Prepayments to CROs	1,031	1,658
Prepaid maintenance	1,128	115
Prepayments to CMOs	31	1,884
Other prepaid expenses and current assets	45	31
Total prepaid expenses and other current assets	<u>\$ 3,649</u>	<u>\$ 4,709</u>

6. Property and Equipment, net

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

	Useful life (in years)	March 31, 2022	December 31, 2021
Laboratory equipment	3	\$ 5,641	\$ 5,502
	Lesser of useful life or lease term		
Leasehold improvements		1,606	1,614
Furniture and fixtures	3	303	303
Construction in progress	—	16,328	13,014
Computer equipment	3	166	216
Software	3	328	320
		<u>24,372</u>	<u>20,969</u>
Less: Accumulated depreciation and amortization		(6,636)	(6,326)
Property and equipment, net		<u>\$ 17,736</u>	<u>\$ 14,643</u>

Depreciation and amortization expense was \$0.4 million and \$0.3 million for the three months ended March 31, 2022 and 2021, respectively. Construction in progress has increased by \$3.3 million during the three months ended March 31, 2022 due to building construction related to the Company's leased space in Redwood City, California. Construction in process is expected to continue to increase through the first half of 2022, until completion of the construction in the third quarter of 2022.

On March 18, 2022, the Company's wholly-owned subsidiary Adicet Therapeutics entered into Change Order No. 3 (the Change Order No. 3) to a construction agreement between Adicet Therapeutics and CP Enterprises, Inc. d/b/a CP Construction (CP Construction) (the Construction Agreement). The Construction Agreement provides for pre-construction and construction services at the Company's office and laboratory space in Redwood City, California (1000 Bridge Parkway) for consideration of approximately \$13.8 million to CP Construction, including previous change orders. The Change Order No. 3 increased the budget for the construction by approximately \$5.3 million in order to build one GMP cell processing and one vector manufacturing suite in addition to controlled materials warehousing at 1000 Bridge Parkway.

7. Accrued and Other Current Liabilities

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

	March 31, 2022	December 31, 2021
Accrued compensation	\$ 2,314	\$ 4,020
Accrued CMO costs	1,617	1,077
Accrued professional services	783	546
Accrued other research and development expenses	418	504
Accrued other liabilities	53	503
Accrued CRO costs	18	32
Total accrued and other liabilities	<u>\$ 5,203</u>	<u>\$ 6,682</u>

8. Regeneron License and Collaboration Arrangement

Agreement Terms

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, 2022. In addition, Regeneron may have to pay the Company additional amounts in the future consisting of up to an aggregate of \$100.0 million of option exercise fees, as specified in the Regeneron Agreement. Regeneron must also pay the Company high single digit royalties as a percentage of net sales for 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.

Equity Investments. In connection with its collaboration, Regeneron and the Company entered into a side letter pursuant to which, among other matters, Regeneron was granted certain stockholder rights and investment rights in connection with the Company's next equity financing that met certain criteria and in connection with an initial public offering by the Company. Regeneron exercised its investment right and purchased approximately \$10.0 million of the Company's Series B redeemable convertible preferred stock in a private placement transaction in July 2019. The remaining obligations under the side letter agreement terminated immediately prior to the closing of the merger with resTORbio.

Revenue Recognition

The Company identified the following material promises under the Regeneron Agreement: (1) a research license, (2) a collaboration invention license, (3) a trademark license, (4) research and development services during the research term, (5) manufacturing services to manufacture collaboration ICPs for the research programs, (6) participation in the joint research committee, and (7) information sharing during the research term. The Company considered that the licenses granted under the Regeneron Agreement are not capable of being distinct and are not distinct from the research and development and manufacturing services within the context of the Regeneron Agreement, because 1) such licenses are for the research and development effort during the research term, unless Regeneron exercises its option under the Regeneron Agreement, 2) the research and development services significantly increase the utility of such licenses, and 3) research and development services require collaboration ICPs being manufactured. Specifically, the Company's granted licenses can only provide benefit to Regeneron in combination with the Company's research and development and manufacturing services to discover the collaboration ICPs. Similarly, the participation in the joint research committee and information sharing are not capable of being distinct and are not distinct from the research and development and manufacturing services within the context of the agreement, because the participation in the joint research committee is for monitoring and governing of the research and

development efforts and the information sharing is for sharing results of such research and development efforts. Therefore, all of the promises above are combined into a single performance obligation.

The Company also evaluated whether the option provided to Regeneron represents a material right that would require separate deferral and recognition. The option exercise will provide Regeneron with a development and commercial license to develop and commercialize the optioned collaboration ICPs. The Company concluded that the \$25.0 million upfront payment to the Company was not negotiated to provide incremental discount for the future option fees payable upon Regeneron's exercise of the option.

Regeneron could decide not to exercise the option at its own discretion. The exercise of the option by Regeneron is not certain and is dependent on many factors, such as progress made on the specific option-eligible collaboration ICP, Regeneron's overall assessment of commercial feasibility of the further research, development and commercialization of the option products, availability and cost of alternative programs and products. The option provides Regeneron with a license for intellectual property that will be improved from the inception of the Regeneron Agreement. In addition, the option fee is significant compared to the sum total of the upfront payment and research funding fees in the original Regeneron Agreement. Therefore, the Company determined that the option provided to Regeneron does not represent a material right and that any potential exercise of the option should be accounted as a separate contract. Hence, upon the option exercise by Regeneron the option fee would be allocated to the development and commercial license which would be the only performance obligation in that separate contract and recognized as revenue when control of the license rights is transferred to Regeneron.

For revenue recognition purposes, the Company determined that the duration of the contract is the same as the research term of five years beginning on the execution of the Regeneron Agreement on July 29, 2016. The contract duration is defined as the period during which parties to the contract have present and enforceable rights and obligations. The Company determined that Regeneron faces significant in-substance penalties were it to terminate the Regeneron Agreement prior to the end of the research term.

At contract inception, the Company determined the transaction price of the Regeneron Agreement to be \$55.0 million, consisting of the \$25.0 million upfront payment and the aggregate research funding fees of \$30.0 million payable over the research term. In order to determine the transaction price, the Company evaluated all the payments to be received during the duration of the contract. Per the terms of the original Regeneron Agreement prior to the amendment effective from July 2019, the research funding fees of \$30.0 million were payable merely due to the passage of time and therefore did not represent a variable consideration. After the amendment became effective in July 2019, \$20.0 million of these fees became contingent upon meeting certain development and regulatory milestones. Therefore, the Company concluded that after the amendment such potential payments became variable consideration. The receipt of the variable consideration was subject to substantial uncertainty and was therefore excluded from the transaction price upon the effective date of the amendment. Accordingly, the transaction price was reduced to \$35.0 million in July 2019. The Company re-evaluates the transaction price if there is a significant change in facts and circumstances at least at the end of each reporting period. The Company increased the transaction price by \$10.0 million in June 2020 to \$45.0 million when it achieved the milestone for the selection of a clinical candidate to the second collaboration target under the Regeneron Agreement. The Company recorded a \$4.0 million revenue reduction in the first quarter of 2021 as a result of an adjustment to cumulative revenue recognized due to a change in overall estimated costs primarily due to an extension of time to fulfill the combined performance obligation. During the three months ended March 31, 2022, the Company recorded \$25.0 million in revenue, inclusive of a \$20 million option exercise fee described below.

The Company has determined that the combined performance obligation is satisfied over time. ASC 606 requires the Company to select a single revenue recognition method for the performance obligation that depicts the Company's performance in transferring control of the services. Accordingly, the Company utilizes a cost-based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. The Company believes this is the best measure of progress because it reflects how the Company transfers its performance obligation to Regeneron. In applying the cost-based input method of revenue recognition, the Company uses actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. These costs consist primarily of internal full-time equivalent effort and third-party contract costs. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligations over the research term of five years. For revenue recognition purposes, the five-year term had been extended to the first quarter of 2022 due to additional time required to complete the performance obligations under the Regeneron Agreement. A cost-based input method of revenue recognition requires management to make estimates of costs to complete the Company's performance obligations. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete the Company's performance obligations will be recorded in the period in which changes are identified and amounts

can be reasonably estimated. The Company's obligations under the combined performance obligation were completed during the three months ended March 31, 2022.

The following tables present changes in the Company's contract liabilities for the three months ended March 31, 2022 and 2021 (in thousands):

Three Months Ended March 31, 2022	Balance at Beginning of Period	Additions (Deductions) (1) (2)	Balance at End of Period
Contract liability	\$ 4,805	\$ (4,805)	\$ —

Three Months Ended March 31, 2021	Balance at Beginning of Period	Additions (Deductions) (1) (2)	Balance at End of Period
Contract liability	\$ 13,980	\$ 3,981	\$ 17,961

- (1) Deductions to contract liabilities relate to deferred revenue recognized as revenue during the reporting period.
- (2) Additions are the result of a reduction to cumulative revenue recognized as a result of a change in overall estimated costs, primarily due to an extension of time to fulfill the combined performance obligation, which was recorded as a change in estimate during the three months ended March 31, 2021.

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 by March 31, 2022.

Pursuant to the Regeneron Agreement, upon Regeneron's exercise of the option, the Company had a specified period of time to elect to co-fund future development costs of ADI-002, and to participate in any potential profits with Regeneron up to a specified co-funding percentage in various geographic regions, including on a worldwide basis (Co-Funding Option). The Company elected not to exercise its Co-Funding Option for ADI-002. Accordingly, 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, 2022, there were no contract liabilities related to the Regeneron Agreement. Additionally, As of March 31, 2022, there were no contract assets which would be reflected as accounts receivable-related party on the consolidated balance sheet.

As of March 31, 2021, contract liabilities related to the Regeneron Agreement of \$18.0 million was comprised of the \$25.0 million upfront payment and additional \$5.0 million research funding fees in each of 2017 and 2018, and \$10.0 million for achievement of the milestone for the selection of a clinical candidate to the second collaboration target in June 2020 less \$27.0 million of cumulative license and collaboration revenue recognized from the inception of the Regeneron Agreement as of March 31, 2021.

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, 2022, no qualifying expenses have been incurred and nothing has been funded by the NIH. On a cumulative basis as of March 31, 2022, \$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 Menlo Park, CA, Redwood City, CA, and Boston, MA.

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, 2022 (in thousands):

	<u>March 31,</u> <u>2022</u>
Lease Cost	
Operating lease cost	\$ 1,007
Short-term lease cost	143
Variable lease cost	—
Sublease Income	(167)
Total lease cost	<u>\$ 983</u>
Other Information	
Operating cash flows used for lease liabilities	\$ 511
Operating lease right of use asset obtained in exchange of operating lease liability	\$ —
Weighted-average remaining lease term - operating leases	7.5
Weighted-average discount rate - operating leases	7.1 %

On July 19, 2021, the Company entered into a Sublease (the Sublease Agreement) with RFS OPCO LLC (Sublessee), whereby the Company agreed to sublease to Sublessee all of the 9,501 rentable square feet of office space in Boston, MA, currently leased by the Company pursuant to the Company's lease with 500 Boylston & 222 Berkeley Owner (DE) LLC, dated January 8, 2018, as amended (the Master Lease). The term of the sublease started on September 1, 2021 and ends on July 30, 2026. The aggregate base rent due to the Company under the Sublease is approximately \$3.5 million which began on October 1, 2021. Upon execution of the Sublease Agreement, the Company received a cash security deposit of \$0.1 million from the Sublessee which is recorded as other non-current liabilities in the consolidated balance sheets. The expected sublease income as of March 31, 2022 is as follows (in thousands):

	<u>March 31,</u> <u>2022</u>
2022	\$ 493
2023	671
2024	685
2025	699
2026	416
Total	<u>\$ 2,964</u>

Further, the Company remains liable for the remaining lease payments under the Master Lease, totaling \$3.1 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, 2022 were as follows (in thousands):

	March 31, 2022
2022	\$ 2,582
2023	3,428
2024	3,525
2025	3,625
2026 and thereafter	13,747
Total undiscounted lease payments	26,907
Less: imputed interest	6,324
Total operating lease liability	20,583
Less: current portion	1,733
Operating lease liability, net of current maturities	\$ 18,851

11. Stockholders' Equity

Common Stock

The Company's Certificate of Incorporation, as amended, authorized the Company to issue 150,000,000 shares of \$0.0001 par value common stock as of December 31, 2021.

Common stockholders are entitled to dividends if and when declared by the Board of Directors subject to the prior rights of the preferred stockholders. As of March 31, 2022, 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:

	March 31, 2022	December 31, 2021
Stock options available for future grant	3,531,453	1,961,338
Stock options issued and outstanding	5,376,145	3,875,317
Unvested restricted stock units	538,660	771,660
Common stock warrants issued and outstanding	220,890	220,890
Total common stock reserved	9,667,148	6,829,205

Warrants to Purchase Shares of Common Stock

As of March 31, 2022, the Company's outstanding warrants to purchase shares of common stock, consisted of the following:

Issuance Date	Number of Shares of Common Stock Issuable	Exercise Price	Classification	Expiration Date
September 15, 2020	101,610	\$ 11.3177	Equity	July 25, 2026
September 15, 2020	30,924	\$ 11.3177	Equity	August 21, 2026
September 15, 2020	77,312	\$ 11.3177	Equity	September 19, 2026
September 15, 2020	11,044	\$ 11.3177	Equity	September 26, 2026
	220,890			

12. Stock-based Compensation

Stock-based Compensation Expense

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

	Three Months Ended March 31,	
	2022	2021
Research and development	\$ 1,687	\$ 1,588
General and administrative	2,663	1,455
Total stock-based compensation	<u>\$ 4,350</u>	<u>\$ 3,043</u>

Stock Options

A summary of stock option activity for three months ended March 31, 2022 is set forth below:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2021	3,875,317	\$ 14.08	8.85	\$ 13,212
Options authorized	—			
Options granted	1,555,000	\$ 14.59		
Options exercised	(10,099)	\$ 9.29		
Options forfeited or cancelled	(44,073)	\$ 14.21		
Outstanding, March 31, 2022	<u>5,376,145</u>	\$ 14.24	8.89	\$ 30,825
Options exercisable, March 31, 2022	1,296,481	\$ 13.67	8.45	\$ 8,174
Vested and expected to vest, March 31, 2022	5,376,145	\$ 14.24	8.89	\$ 30,825

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

	Three Months Ended March 31,	
	2022	2021
Fair value of common stock	\$11.93 - \$19.97	\$8.33 - \$11.39
Expected term (years)	5.8 - 6.1	5.9 - 6.1
Volatility	77.4% - 77.7%	79.2% - 79.8%
Risk free rates	1.6% - 2.4%	0.7% - 0.9%
Dividend rate	0.0%	0.0%

Restricted Stock Units

In August 2021, the Company granted 210,750 restricted stock units (RSUs) to employees with a weighted-average grant date fair value of \$7.12 per share.

In October 2021, the Company granted 560,000 RSUs with service and performance conditions to certain employees, 224,000 of which vested during the three months ended March 31, 2022. Vesting of these awards is contingent on the occurrence of certain milestone events and fulfillment 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 \$1.1 million of related expense during the three months ended March 31, 2022.

The summary of RSU activity and related information follows:

	Number of Units Outstanding		Weighted-Average Grant Date Fair Value
Outstanding, December 31, 2021	771,660	\$	7.84
RSUs granted	—		-
RSUs Vested	(224,000)	\$	8.02
RSUs forfeited	(9,000)	\$	7.12
Outstanding, March 31, 2022	<u>538,660</u>	\$	<u>7.75</u>

Summary of Plans

The Company has a 2014 Share Option Plan (the 2014 Plan), 2015 Stock Incentive Plan (the 2015 Plan), 2017 Stock Incentive Plan (the 2017 Plan), 2018 Stock Incentive Plan (the 2018 Plan), and 2018 Employee Stock Purchase Plan (the 2018 ESPP, and, collectively with the 2014 Plan, the 2015 Plan, the 2017 Plan and the 2018 Plan, the Plans). There have been no material changes in the Plans from those disclosed in Note 18 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

The 2017 Plan and 2018 Plan

As of March 31, 2022, the number of shares of common stock available for grant under the 2017 and 2018 Plan is 2,641,835 shares. As of March 31, 2022, an aggregate of 4,234,328 shares of common stock were issuable upon the exercise of outstanding stock options under the 2017 Plan and 2018 Plans at a weighted average exercise price of \$15.03 per share. Included in this amount was a grant of 6,410 PSUs, 210,750 RSUs and 560,000 RSUs the Company granted in May 2021, August 2021 and October 2021, respectively.

The 2014 Plan and 2015 Plan

As of March 31, 2022, the number of shares of common stock available for grant under the 2014 and 2015 Plans is 13,418. As of March 31, 2022, an aggregate of 1,171,193 shares of Former Adicet common stock were issuable upon the exercise of outstanding stock options under the 2015 plan at a weighted average exercise price of \$11.89 per share and an aggregate of 185,396 shares of Former Adicet common stock were issuable upon the exercise of outstanding stock options under the 2014 Plan at a weighted average exercise price of \$1.61 per share.

2018 Employee Stock Purchase Plan

On January 1, 2022, as a result of the foregoing evergreen provision, the number of shares of common stock available for issuance under the 2018 ESPP automatically increased from 524,775 to 922,144 shares. No shares have been issued under the 2018 ESPP during the three months ended March 31, 2022.

Inducement Grant

As of March 31, 2022, an aggregate of 486,303 shares of common stock were issuable upon the exercise of inducement grants of stock options approved by the Company in accordance with Nasdaq listing Rule 5635(c)(4) at a weighted average exercise price of \$14.52 per share.

13. Net Income (Loss) per Share

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

	Three Months Ended March 31,	
	2022	2021
Net income (loss) attributable to common stockholders - basic and diluted	\$ 4,618	\$ (21,319)
Weighted-average shares used in computing net income (loss) per share attributable to common shareholders, basic	39,823,246	26,099,954
Effect of dilutive securities:		
Stock options	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	45,958,941	26,099,954
Net income (loss) per share attributable to common stockholders, basic	\$ 0.12	\$ (0.82)
Net income (loss) per share attributable to common stockholders, diluted	\$ 0.10	\$ (0.82)

For the three months ended March 31, 2021, 4,767,007 options to purchase common stock and 220,890 common stock warrants 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, 2022, compared to an income tax benefit of \$48,000 during the three months ended March 31, 2021. The income tax benefit during the three months ended March 31, 2021 was due to the tax effect of the reduction in the deferred tax liability associated with the basis differences from IPR&D.

The Company maintains a full valuation allowance against its deferred tax assets due to the Company's history of losses as of March 31, 2022.

15. Related Party

As of March 31, 2022, Regeneron owned 883,568 shares of the Company's common stock, respectively. 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, 2022, the Company recorded revenue from the Regeneron Agreement of \$25.0 million. 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, 2021. 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 T cell receptor-like antibodies (TCRL), to enhance selective tumor targeting, facilitate innate and adaptive anti-tumor immune response, and improve persistence 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 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 Non-Hodgkin’s lymphoma (NHL). Our pipeline also includes ADI-002, an allogeneic gamma delta CAR-T cell therapy expressing a GPC3-targeted CAR and a cell intrinsic soluble form of interleukin-15 (IL-15), for the treatment of solid tumors. In addition, we are engaged in discovery and preclinical stage activities directed to expansion of our pipeline of product candidates for both hematological malignancies and solid tumors.

Our proprietary engineering and manufacturing process begins with isolating and expanding gamma delta T cells from the blood of unrelated donors, and results in the potential to treat up to 1,000 patients per batch depending on dosing and the CAR target. The potential to administer product candidates based on gamma delta T cells to patients without inducing a graft versus host immune response could mean that our product candidates can potentially be used as “off-the-shelf” therapies. 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. Based on what we believe is the unique potential of these cells and associated modifications, we are initially developing product candidates in oncology, both for hematological malignancies and for solid tumors. In October 2020, the U.S. Food and Drug Administration (FDA) cleared our Investigational New Drug (IND) application for ADI-001, our lead product candidate, for the treatment of NHL. In March 2021, we initiated the first-in-human clinical trial to assess safety and efficacy of ADI-001 in NHL patients. The Phase 1 study for ADI-001 will 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 December 2021, we announced positive interim clinical data from the initial dose escalation portion of this study. We expect to report updated interim data for the Phase 1 study of ADI-001 at the American Society of Clinical Oncology (ASCO) annual meeting on June 6, 2022. In April 2022, the FDA granted Fast Track Designation for ADI-001 for NHL.

Recent Developments

Public Offerings and Private Placement

In February 2021, we completed an underwritten public offering of 10,575,513 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to an additional 1,344,743 shares of common stock at a public offering price of \$13.00 per share. The net proceeds from the offering, after deducting underwriting discounts and commissions and offering expenses were approximately \$128.8 million.

In connection with the February 2021 offering, we also entered into a stock purchase agreement with certain existing investors to purchase 1,153,840 shares of our common stock for \$15.0 million at a price per share equal to the public offering price, with an initial closing for certain investors held simultaneously with the closing of the offering and a subsequent closing for certain additional investors. We received the full proceeds from the sale and did not pay any underwriting discounts or commissions with respect to the shares of common stock that sold in the concurrent private placement. Pursuant to the terms

of the private placement, we subsequently filed a Registration Statement on Form S-3 (File No. 333-256088), dated May 21, 2021, pursuant to which we registered the Private Placement Shares. We have agreed to maintain the effectiveness of the registration statement until such time as all Private Placement Shares covered by the registration statements have been sold or may be sold under Rule 144 without manner of sale restrictions or volume limitations, subject to certain exceptions.

In December 2021, we completed an underwritten public offering of 7,187,500 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to an additional 937,500 shares of common stock, at a public offering price of \$14.00 per share. The net proceeds from the offering, after deducting underwriting discounts and commissions and offering expenses, were approximately \$94.2 million.

At-the-Market (ATM) Offering

On March 12, 2021, we entered into a Sales Agreement (the 2021 Sales Agreement) with JonesTrading Institutional Services (the Agent), 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 Agent, as our sales agent. No shares were sold under the 2021 Sales Agreement as of March 31, 2022.

Loan Agreement

On October 21, 2021, we amended our Loan and Security Agreement (the Loan Agreement) with Pacific Western Bank (PacWest) (the Loan Amendment) under which PacWest will provide one or more term loans (the Term Loans), 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. As of March 31, 2022, we had outstanding Non-Formula Ancillary Services of \$4.4 million. Accordingly, as of March 31, 2022, we had \$10.6 million available under the Term Loan. Pursuant to the 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 (as defined in the Loan Agreement) then in effect and (ii) 4.25%.

Change Order for 1000 Bridge Parkway Construction

On March 18, 2022, our wholly-owned subsidiary Adicet Therapeutics, Inc. (Adicet Therapeutics) entered into Change Order No. 3 (the Change Order No. 3) to a construction agreement between Adicet Therapeutics and CP Enterprises, Inc. d/b/a CP Construction (CP Construction) (the Construction Agreement). The Construction Agreement provides for pre-construction and construction services at our office and laboratory space in Redwood City, California (1000 Bridge Parkway) for consideration of approximately \$13.8 million to CP Construction, including previous change orders. The Change Order No. 3 increased the budget for the construction by approximately \$5.3 million in order to build one GMP cell processing and one vector manufacturing suite in addition to controlled materials warehousing at 1000 Bridge Parkway.

Impact of COVID-19 Pandemic

In December 2019, a novel strain of coronavirus, COVID-19, was reported in China. The spread of COVID-19 from China to other countries resulted in the World Health Organization (WHO) declaring the outbreak of COVID-19 as a “pandemic,” or a worldwide spread of a new disease, on March 11, 2020. Since then, COVID-19 has spread globally and new variants of the virus have emerged. Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses. The continued spread of COVID-19, despite progress in vaccination efforts, has resulted in significant governmental measures being implemented to control the spread of COVID-19 and its variants. These measures may result in a period of business, supply, and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations.

In response to the COVID-19 pandemic, we tasked members of our Executive Leadership team, Human Resources, Facilities and Operations and Employee Communications to develop guidelines and processes intended to raise awareness of new health and well-being protocols and potentially helpful practices for cross-functional teamwork for our employees. We implemented remote working and shift scheduling, provided our team members practical recommendations based on guidelines from the Centers for Disease Control and Prevention, State of California Department of Health Care Services, State of Massachusetts Department of Public Health, OSHA and other regional government entities. In addition, we are committed to updating these recommendations and communicating new pertinent information when available. While doing so we are sensitive to ensuring any guidance provided may vary by locality based on government orders and regulations.

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 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 ongoing COVID-19 pandemic on clinical trials generally, and on our trials particularly, is currently unknown.

In addition, the spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 and its 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, and marketable debt securities.

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 are generated from our License and Collaboration Agreement with Regeneron Pharmaceuticals, Inc. (Regeneron) and the agreement referred to as the "Regeneron Agreement". The primary purpose of the Regeneron Agreement is to establish a strategic relationship to identify and validate appropriate targets and work together to develop a pipeline of engineered immune cell products (Collaboration ICPs) for the selected targets. The Regeneron Agreement provides for the following: (i) licenses to our technology, (ii) research and development services, (iii) services or obligations in connection with participation in the research committee, (iv) information sharing, and (v) manufacturing services to manufacture of Collaboration ICPs for the research programs. The Regeneron Agreement provides Regeneron an option to obtain an exclusive, royalty-bearing development and commercial license under our intellectual property to develop and commercialize the optioned Collaboration ICPs ready for an IND submission.

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, 2022. In addition, 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 Collaboration 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 use 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 use actual costs incurred relative to budgeted costs to fulfill the combined performance obligation. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as we complete our performance obligations over the research term of five years. 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, contract manufacturing organizations (CMOs) and contract research organizations (CROs);
- lab materials, supplies, and maintenance of equipment used for research and development activities; and
- allocated facility-related costs, such as rent, utilities, insurance, repairs and maintenance, depreciation and amortization, information technology costs and general support services.

We 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 income earned on our cash and cash equivalents and marketable debt securities.

Interest Expense

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

Other Expense, Net

Other income (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, 2022 and 2021

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

	Three Months Ended March 31,		Change	% Change
	2022	2021		
Revenue – related party	\$ 24,990	\$ (3,981)	\$ 28,971	(728 %)
Operating expenses				
Research and development	13,483	11,743	1,740	15 %
General and administrative	6,801	5,630	1,171	21 %
Total operating expenses	20,284	17,373	2,911	17 %
Income (loss) from operations	4,706	(21,354)	26,060	(122 %)
Interest income	32	41	(9)	(22 %)
Interest expense	(18)	(50)	(32)	(64 %)
Other expense, net	(102)	(4)	(98)	(2,450 %)
Income (loss) before income tax benefit	4,618	(21,367)	25,985	(122 %)
Income tax provision (benefit)	—	(48)	48	(100 %)
Net income (loss)	<u>\$ 4,618</u>	<u>\$ (21,319)</u>	<u>\$ 25,937</u>	<u>(122 %)</u>

Revenue

Revenue increased by \$29.0 million, or 728%, for the three months ended March 31, 2022 compared to the same period in 2021 resulting from the increase in revenue recognized under the Regeneron Agreement. The increase was 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. Additionally, during the three

months ended March 31, 2021, there was a change in estimate related to the estimated costs to complete the Company's performance obligations related to the Regeneron Agreement, which resulted in negative revenue during the period.

Research and development

	Three Months Ended March 31,	
	2022	2021
Payroll and personnel expenses ⁽¹⁾	\$ 6,554	\$ 5,944
Costs incurred under agreements with consultants, CMOs, and CROs	3,384	3,018
Lab materials, supplies, and maintenance of equipment used for research and development activities	1,459	1,055
Other research and development expenses ⁽²⁾	2,086	1,726
Total research and development expenses	\$ 13,483	\$ 11,743

(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 \$1.7 million, or 15%, during the three months ended March 31, 2022 compared to the same period in 2021. The increase in research and development expenses was primarily due to a \$0.6 million increase in payroll and personnel expenses resulting from an increase in overall headcount, a \$0.4 million increase in lab supplies and consumables expenses and \$0.4 million increase in CMO and other externally sponsored research and development expense. In addition, there was a \$0.4 million increase in facility and other expenses for the period. This was partially offset by a \$0.2 million decrease in CRO expense related to initial setup fees for our Phase 1 trial.

General and administrative

General and administrative expenses increased by \$1.2 million, or 21%, during the three months ended March 31, 2022 as compared to the same period in 2021. The increase in general and administrative expenses was primarily due a \$1.5 million increase in payroll and personnel fees, which includes an increase in stock based compensation of \$1.2 million, salaries and benefits of \$0.2 million and recruiting fees of \$0.1 million. These increases were the result of increased headcount for the period. This increase was partially offset by a \$0.3 million decrease in professional service fees, which includes a \$0.3 million decrease in audit fees related to the merger with resTORbio, Inc, offset by a less than \$0.1 million increase in legal fees.

Interest income

Interest income decreased by less than \$0.1 million, or 22%, during the three months ended March 31, 2022 as compared to the same period in 2021, which was primarily due to sales of our marketable debt securities prior to 2022.

Interest Expense

Interest expense decreased by less than \$0.1 million or 64% during the three months ended March 31, 2022 as compared to the same period in 2021 due to the straight-line non-cash amortization of costs incurred in connection with the Loan Agreement entered into in April 2020, and subsequently amended in October 2021.

Other expense, net

Other expense, net increased by \$0.1 million, during the three months ended March 31, 2022 as compared to the same period in 2021. For the quarter ended March 31, 2022, we recorded franchise taxes of approximately \$65,000. Additionally, we recorded realized losses related to foreign exchange currency of approximately \$20,000 and a loss from disposal of assets of approximately \$18,000. For the quarter ended March 31, 2021, we incurred realized losses related to foreign exchange of approximately \$18,000.

Income tax expense

We recognized no income tax expense during the three months ended March 31, 2022 compared to an income tax benefit of \$48,000 during the three months ended March 31, 2021. The income tax benefit of \$48,000 was due to the tax effect of the reduction in the deferred tax liability associated with the basis differences from in process research and development (IPR&D) for the three months ended March 31, 2021.

Liquidity and Capital Resources

Sources of Liquidity

Since our formation in 2014, we have funded our operations with an aggregate of \$116.3 million in gross cash proceeds from the sale of redeemable convertible preferred stock and an aggregate of \$45.0 million received to date from Regeneron under the Regeneron Agreement. In September 2020, following the closing of the merger, all outstanding shares of the redeemable convertible preferred stock converted into 12,048,671 shares of common stock. We also acquired \$64.1 million of cash, cash equivalents and restricted cash owned by resTORbio, as part of the merger. In February 2021, we completed an underwritten public offering of 10,575,513 shares of our common stock at a public offering price of \$13.00 per share. The aggregate gross proceeds from the offering, before deducting underwriting discounts and commissions and offering expenses were approximately \$137.5 million. In connection with the offering, we also entered into a stock purchase agreement with certain existing investors for \$15.0 million of shares of our common stock at a price per share equal to the public offering price, with an initial closing for certain investors held simultaneously with the closing of the offering and a subsequent closing for certain additional investors.

In March 2021, we entered into the 2021 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 JonesTrading Institutional Services, LLC as our sales agent. As of March 31, 2022, no shares have been sold under the 2021 Sales Agreement.

In December 2021, we completed an underwritten public offering of 7,187,500 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to an additional 937,500 shares of common stock, at a public offering price of \$14.00 per share. The net proceeds from the offering, after deducting underwriting discounts and commissions and offering expenses were approximately \$94.2 million.

As of March 31, 2022, we had cash and cash equivalents of \$277.9 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 (the Loan Amendment) under which PacWest will provide one or more Term Loans, 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. As of March 31, 2022, we had outstanding Non-Formula Ancillary Services of \$4.4 million. Accordingly, as of March 31, 2022, the Company has \$10.6 million available under the Term Loan. Pursuant to the 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 income of \$4.6 million for the three months ended March 31, 2022. Prior to this period, we have recorded net losses since inception. As of March 31, 2022, we had an accumulated deficit of \$163.7 million.

As of March 31, 2022, we had cash and cash equivalents of \$277.9 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 is 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 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 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.

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):

	Three Months Ended March 31,	
	2022	2021
Net cash provided by (used in):		
Operating activities	\$ 4,105	\$ (15,146)
Investing activities	(2,632)	7,842
Financing activities	(1,134)	144,887
Net increase in cash, cash equivalents and restricted cash	\$ 339	\$ 137,583

Cash Flows from Operating Activities

Net cash provided by operating activities was \$4.1 million for the three months ended March 31, 2022. Cash provided in operating activities consisted of net income of 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.

Net cash used in operating activities was \$15.1 million for the quarter ended March 31, 2021. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of \$21.3 million, adjusted for non-cash activities of \$8.3 million. The non-cash activities are composed of depreciation expense of \$0.3 million, a non-cash lease expense of \$0.7 million related to amortization of right of use, stock-based compensation expense of \$3.0 million, a non-cash expense for impairment of IPR&D of \$0.5 million, a gain on the remeasurement of contingent consideration liability of \$0.4 million, amortization of the deferred debt issuance cost of \$0.2 million, and reduction to revenue of \$4.0 million. Changes in operating assets and liabilities were composed of a decrease in lease liabilities of \$0.4 million, and a decrease in accrued and other current liabilities of \$1.6 million, partially offset by an increase in other non-current assets of \$0.4 million and an increase in accounts payable of \$0.2 million. Increases in accounts payable and decreases in accrued and other liabilities resulted from the timing of payments to our service providers.

Cash Flows from Investing Activities

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

Net cash used in investing activities for the three months ended March 31, 2021 was \$7.8 million, which included proceeds from the sale of marketable securities of \$7.5 million and proceeds from the maturities of marketable securities of \$1.0 million. This was partially offset by purchases of property and equipment of \$0.7 million.

Cash Flows from Financing Activities

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 to 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 than \$0.1 million.

Net cash provided by financing activities was \$144.9 million for the three months ended March 31, 2021, was related to net cash proceeds received from our public offering in February 2021 of \$143.8 million, cash proceeds of \$1.0 million from exercise of stock options and deferred debt issuance costs of \$0.2 million.

Leases

We currently lease an office space in Boston, MA 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, MA. The term of the sublease 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.

We also have an office facility in Menlo Park, CA under a non-cancellable operating lease (the Menlo Park Lease), with an expiration date of March 31, 2022 (subject to any optional extension). This lease was amended on June 25, 2021 to extend the term of lease from March 31, 2022 to June 30, 2022 and replace the previously leased premises (known as 173 and 175-177 Jefferson Drive) with a nearby premises (known as 235 Constitution Drive). The lease commenced on July 15, 2021 and expires on June 30, 2022. In connection with these changes, we incur monthly rent payments ranging from \$87,286 to \$89,904, increasing over the remaining term of the lease. This lease was amended on September 30, 2019 to include additional office space, with an expiration date of March 31, 2022 (subject to any optional extension). The initial annual base rent for the Menlo Park Lease is an aggregate of \$1.0 million, and such amount will increase 3% annually. On October 28, 2018, we executed an additional non-cancelable lease agreement for a new office and laboratory facility in Redwood City, CA (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 July 30, 2021, we entered a short-term lease agreement with the Boston Properties, Inc. for a temporary office space located at 200 Clarendon Street, Boston, Massachusetts (the Boston Lease). The initial lease term commenced on July 30, 2021 and expired on November 30, 2021. In February 2022, we extended the lease term to expire on July 31, 2022. The base rent is approximately \$9,000 per month.

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 CMO, CRO and research and development expenses, equity-based compensation, valuation of the IPR&D and the contingent value rights agreement (applicable through the quarter ending March 31, 2021), as discussed in our unaudited consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, determination of the fair value of common shares prior to our Merger are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future (applicable through the quarter ending March 31, 2021). 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, 2021 filed with the SEC on March 15, 2022.

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 \$1.07 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, 2022, we had cash and cash equivalents of \$277.9 million, consisting of interest-bearing money market funds, for which the fair value would be affected by changes in the general level of U.S. interest rates. However, due to the short-term maturities and the low-risk profile of our cash equivalents, an immediate 10% relative change in interest rates would not have a material effect on the fair value of our cash equivalents or on our future interest income.

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. As of March 31, 2022, 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. As of March 31, 2022, we do not believe that inflation has had a material effect on our business, financial condition or results of operations.

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 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, 2022, 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 Securities Exchange Act of 1934) 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, 2022 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, 2022, 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, 2022, our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, 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, 2021.*

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 operation 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.

Prior to this period we incurred net losses in every period 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 in each period 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. Although we recorded net income of \$4.6 million for the three months ended March 31, 2022, this was primarily due to the completion of a milestone under the Regeneron Agreement (as defined below) related to ADI-002 which resulted in a \$20.0 million payment received. As of March 31, 2022, we had an accumulated deficit of \$163.7 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. 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 our existing cash and cash equivalents we are able to fund our expenses and capital expenditure requirements beyond twelve months from the issuance of the accompanying unaudited consolidated financial statements and into the second half of 2024. 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 own 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 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 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 successful development, manufacturing, positive efficacy and safety profile in our clinical trials, regulatory approval and commercialization of our novel product candidates, which may never occur. We have not yet succeeded and may not succeed in demonstrating efficacy and safety 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, 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 CAR-T 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 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 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 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, including ADI-001 and ADI-002, 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 ADI-001 and ADI-002 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. 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 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 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 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 Practice (GCP) requirements or applicable regulatory guidelines in other countries;
- transfer of manufacturing processes to any new contract manufacturing organization (CMO) or our own 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 and ADI-002 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 ongoing 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 ongoing COVID-19 pandemic. We believe that the coronavirus 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 product candidates, including approved autologous CAR-T products. Our therapies may not be as safe and effective as autologous CAR-T therapies and may only be approved for patients who are ineligible for autologous CAR-T 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. Developing, obtaining regulatory approval 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, 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 chimeric antigen receptor (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 do not currently operate our own 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 do not currently own or operate any manufacturing facilities. We rely, and expect to continue to rely, 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 CMOs, 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. 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 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 the 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. We will need substantial additional financing to develop our products and implement our operating plans. In particular, we will require substantial additional financing to enable commercial production of our products and initiate and complete registration trials for multiple products. Further, if approved, we will require significant additional amounts in order to launch and commercialize our product candidates.

As of the date of this Quarterly Report on Form 10-Q, we believe that with our existing cash and cash equivalents we are able to fund our expenses and capital expenditure requirements beyond twelve months from the issuance of the accompanying unaudited consolidated financial statements and into the second half of 2024. 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, 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 CMO, 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 ongoing COVID-19 pandemic, may materially and adversely affect our business and operations.

Our business, financial position, results of operations or cash flows may be affected by the ongoing global COVID-19 pandemic and the resulting volatility and uncertainty it has caused, and is likely to continue to cause, in the United States and international markets, including as a result of prolonged economic downturn or recession. Since January 2020, the COVID-19 pandemic has spread around the world. The continued spread of COVID-19, despite progress in vaccination efforts, has resulted in significant governmental measures being implemented to control the spread of COVID-19 and its variants, including quarantines, travel restrictions, social distancing and business shutdowns. Such measures have had, and are likely to 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, the COVID-19 pandemic has affected and may further 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. The ongoing COVID-19 pandemic is also likely to directly or indirectly impact the pace of enrollment in our future 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 COVID-19 patients, 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 the COVID-19 pandemic are difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity.

The extent to which the ongoing COVID-19 pandemic may continue to impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration and severity of the pandemic, including the continued emergence of new variants, developments or perceptions regarding the safety of vaccines, or any additional preventative and protective actions taken to contain the pandemic or treat its impact. We do not yet know the full extent of potential delays or impacts on our business, financing, or clinical trial activities or on healthcare systems or the global economy as a whole. However, any of the foregoing risks, or other unforeseen risks related to the COVID-19 pandemic, could have a material impact on our liquidity, capital resources, operations, and business and those of the third parties on which it relies.

****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 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 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 supplies 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 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 routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. 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.

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) as well as comprehensive privacy laws in Colorado and Virginia will become effective in 2023. 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 data in the European Union (EU) are governed by the GDPR. The GDPR imposes stringent requirements for controllers and processors of personal data, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations when we contract with third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other third countries. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

The GDPR applies extraterritorially, and we may be subject to the GDPR because of our data processing activities that involve the personal data of individuals located in the European Union, such as in connection with our EU clinical trials. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. GDPR regulations may impose additional responsibility and liability in relation to the personal data that our processes and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities, 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 Litigation

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.

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 Pacific Western Bank, as amended on October 21, 2021 (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, 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 Pacific Western Bank and issued a warrant to purchase our capital stock. Our failure to comply with the covenants in the Loan Agreement, 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 Pacific Western Bank's lien on our assets, as determined by Pacific Western Bank, 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 Pacific Western Bank, 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) stimulate further corporate growth or development through the assumption of additional debt; or (d) 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 Pacific Western Bank are not satisfied, 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.

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 \$1.07 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 below \$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, as amended, or the IRC, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity 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. 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, 2021, we had federal net operating loss carryforwards of approximately \$271.6 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above.

Comprehensive tax reform legislation 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, or 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, 2021, 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 by March 31, 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, that we believe can provide us with additional capabilities beneficial to our business. The collaboration with Regeneron provides us with important technologies, expertise and funding for our programs and technology, and we expect to receive additional technologies, expertise and funding under this and 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.
- Our third-party manufacturers could breach or terminate their agreement(s) with us.

If any CMO 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 CMO, 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 CMO 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 CMOs for any reason, we will be required to verify that the new CMO 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 CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidates that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO 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. Additionally, since the beginning of the COVID-19 pandemic, three vaccines for COVID-19 have received Emergency Use Authorization by the FDA, and two of those later received marketing approval. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the materials needed for our clinical trials, which could lead to delays in these trials.

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 ongoing 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 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 or other comparable foreign regulatory authorities;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, 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 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 ongoing 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 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 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 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 its 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 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.

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

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

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

From time to time, we may publish interim, top-line or preliminary results from our preclinical studies or clinical trials. Such clinical results are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. 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.

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, or 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 inspections to assess compliance with cGMPs and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. 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; 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 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.

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, 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 payors 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 payors 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.

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.

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. 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 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 or 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 in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop 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 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. 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;
- 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 43.8% 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, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. 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.

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 behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company's 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 the Company governed by the internal affairs doctrine. 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 \$1.07 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. 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, cash equivalents, and marketable securities and may not use them effectively.

Our management has broad discretion to use our cash, cash equivalents, and marketable securities 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, cash equivalents, and marketable securities 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.

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 our common stock from time to time in “at-the-market” offerings under the 2021 Shelf Registration Statement and subject to the limitations thereof. We will pay to the Sales Agent cash commissions of 3% 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 also filed a registration statement 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 this registration statement 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

Exhibit Number	Description
3.1	<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>
3.2	<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>
3.3	<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>
3.4	<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>
10.1	<u>Change Order No. 1, dated September 23, 2021, by and between Adicet Therapeutics, Inc. and CP Enterprises, Inc. d/b/a CP Construction (incorporated by reference to Exhibit 10.1 to the Registrant’s Current Report on Form 8-K (File No. 001-38359) filed with the SEC on March 24, 2022).</u>
10.2	<u>Change Order No. 2, dated March 18, 2022, by and between Adicet Therapeutics, Inc. and CP Enterprises, Inc. d/b/a CP Construction (incorporated by reference to Exhibit 10.2 to the Registrant’s Current Report on Form 8-K (File No. 001-38359) filed with the SEC on March 24, 2022).</u>
10.3	<u>Change Order No. 3, dated March 18, 2022, by and between Adicet Therapeutics, Inc. and CP Enterprises, Inc. d/b/a CP Construction (incorporated by reference to Exhibit 10.3 to the Registrant’s Current Report on Form 8-K (File No. 001-38359) filed with the SEC on March 24, 2022).</u>
31.1*	<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>
31.2*	<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>
32.1**	<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>
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

* 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 12, 2022

By:

/s/ Chen Schor

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

Date: May 12, 2022

By:

/s/ Nick Harvey

Nick Harvey
Chief Financial Officer
(Principal financial and accounting officer)

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

I, Chen Schor, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Adicet Bio, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Chen Schor

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

Date: May 12, 2022

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

I, Nick Harvey, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Adicet Bio, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Nick Harvey

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

Date: May 12, 2022

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, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, that, to the best of their knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Chen Schor

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

Date: May 12, 2022

/s/ Nick Harvey

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

Date: May 12, 2022
