

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

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	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	ACET	The Nasdaq Global Market

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

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

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

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

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

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

As of November 9, 2021, the registrant had 31,955,450 shares of common stock, \$0.0001 par value per share, outstanding.

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Summary of the Material Risks Associated with Our Business

- 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. Specifically, our gamma delta T cell candidates represent a novel approach to cancer treatment that creates significant challenges for us.
- Our business is highly dependent on the success of ADI-001 and ADI-002. If we are unable to obtain regulatory approval for ADI-001 or ADI-002 and effectively commercialize ADI-001 or ADI-002 for the treatment of patients in our targeted indications, our business would be significantly harmed.
- All of our product candidates, including ADI-001 and ADI-002, will require additional clinical and non-clinical development and will require substantial investment. If we are unable to raise sufficient capital when needed, our business, financial condition and results of operations will be harmed, and we will need to significantly modify our operational plans to continue as a going concern.
- 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 and ADI-002. 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.
- 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 encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect.
- A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business.
- A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and operations.
- We have identified material weaknesses in our internal control over financial reporting. Failure to achieve and maintain effective internal control over financial reporting could harm our business and negatively impact the value of our common stock.
- 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.
- If our collaboration agreement with Regeneron is terminated, or if Regeneron materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition would be materially harmed.
- We are subject to certain exclusivity obligations under our agreement with Regeneron.
- 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.
- 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 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.

EXPLANATORY NOTE

Prior to September 15, 2020, we were a clinical-stage biopharmaceutical company known as resTORbio, Inc. (resTORbio) that had historically focused on developing innovative medicines that target the biology of aging, to prevent or treat age-related diseases with the potential to extend healthy lifespans. resTORbio was originally incorporated under the laws of the State of Delaware in July 2016 and commenced research and development operations in March 2017.

On September 15, 2020, we completed our business combination whereby a wholly-owned subsidiary of resTORbio merged with and into Adicet Bio, Inc. (Former Adicet), with Former Adicet surviving as a wholly-owned subsidiary of resTORbio and changing our name to Adicet Therapeutics, Inc. (such transactions, the Merger). In connection with the completion of the Merger, resTORbio was renamed Adicet Bio, Inc. (Adicet Bio).

Immediately prior to the Effective Time of the Merger, resTORbio effected a reverse stock split of our common stock at a ratio of 1-for-7 (the Reverse Stock Split). At the Effective Time of the Merger, each outstanding share of Former Adicet's capital stock was converted into the right to receive 0.1240 (the Exchange Ratio) shares of Adicet Bio's common stock.

Unless otherwise noted, all references to common stock share and per share amounts in this Quarterly Report on Form 10-Q have been retroactively adjusted to reflect the conversion of shares in the Merger based on the Exchange Ratio and Reverse Stock Split. As used herein, the words "the Company," "we," "us," and "our" refer to, for periods following the Merger, Adicet Bio (formerly resTORbio, Inc.), together with its direct and indirect subsidiaries, and for periods prior to the Merger, Adicet Therapeutics, Inc. (formerly Adicet Bio, Inc.), and our direct and indirect subsidiaries, as applicable. In addition, the word "resTORbio" refers to the Company prior to the completion of the Merger, and we sometimes refer to Adicet Therapeutics, Inc. as "Adicet" or "Former Adicet."

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- the anticipated timing of our initiation of future clinical trials for ADI-001 in Non-Hodgkin’s Lymphoma (NHL), including the anticipated results;
- the anticipated timing of our submission of our Investigational New Drug (IND) application or equivalent regulatory filings and initiation of future clinical trials for ADI-002 in solid tumors, including the timing of the anticipated results;
- the impacts of the current 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, potential delays and increased costs in conducting clinical trials in nursing homes, and other matters related to our business and operations;
- the timing of announcements of interim results of our clinical trials;
- 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;
- 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 remediate the material weaknesses in internal control over financial reporting and to maintain effective internal control over financial reporting;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;

- developments relating to our competitors and our industry;
- 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)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 192,226	\$ 84,330
Short-term marketable debt securities	—	10,284
Prepaid expenses and other current assets	6,799	5,722
Total current assets	199,025	100,336
Property and equipment, net	11,395	2,790
Operating lease right-of-use asset	20,865	23,066
Goodwill	19,462	20,089
In-process research and development	—	1,190
Restricted cash	4,527	4,527
Other non-current assets	1,921	1,837
Total assets	<u>\$ 257,195</u>	<u>\$ 153,835</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,631	\$ 1,552
Contract liabilities — related party, current	10,088	13,980
Accrued and other current liabilities	4,601	5,732
Operating lease liability	712	1,215
Total current liabilities	20,032	22,479
Operating lease liability, net of current portion	19,823	20,424
Contingent consideration liability	—	980
Deferred tax liability	—	125
Other non-current liabilities	116	—
Total liabilities	<u>39,971</u>	<u>44,008</u>
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized as of September 30, 2021 and December 31, 2020, respectively; none issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, \$0.0001 par value, 150,000,000 shares authorized as of September 30, 2021 and December 31, 2020, respectively; 31,955,050 and 19,677,249 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	3	2
Additional paid-in capital	369,732	216,126
Accumulated deficit	(152,511)	(106,325)
Accumulated other comprehensive income	—	24
Total stockholders' equity	<u>217,224</u>	<u>109,827</u>
Total liabilities and stockholders' equity	<u>\$ 257,195</u>	<u>\$ 153,835</u>

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue—related party	\$ 3,429	\$ 3,028	\$ 4,262	\$ 12,493
Operating expenses:				
Research and development	11,926	8,942	34,285	24,651
General and administrative	5,213	7,741	15,868	17,684
Total operating expenses	17,139	16,683	50,153	42,335
Loss from operations	(13,710)	(13,655)	(45,891)	(29,842)
Interest income	4	153	54	704
Interest expense	(50)	(50)	(151)	(84)
Other income (expense), net	(246)	(1,224)	(312)	(1,174)
Loss before income tax expense (benefit)	(14,002)	(14,776)	(46,300)	(30,396)
Income tax expense (benefit)	11	3	(114)	(2,676)
Net loss	\$ (14,013)	\$ (14,779)	\$ (46,186)	\$ (27,720)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.44)	\$ (2.84)	\$ (1.54)	\$ (8.69)
Weighted-average common shares used in computing net loss per share attributable to common stockholders, basic and diluted	31,876,016	5,208,887	29,954,616	3,190,557
Other comprehensive income (loss):				
Unrealized (loss) gain on marketable debt securities, net of tax	—	(114)	(24)	60
Total other comprehensive (loss) income	—	(114)	(24)	60
Comprehensive loss	\$ (14,013)	\$ (14,893)	\$ (46,210)	\$ (27,660)

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

ADICET BIO, INC.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
	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>
Issuance of common stock upon exercise of stock options	39,603	—	279	—	—	279
Stock-based compensation expense	—	—	2,659	—	—	2,659
Net loss	—	—	—	(10,854)	—	(10,854)
Other comprehensive loss	—	—	—	—	(2)	(2)
Balance at June 30, 2021	<u>31,842,002</u>	<u>\$ 3</u>	<u>\$ 366,836</u>	<u>\$ (138,498)</u>	<u>\$ —</u>	<u>\$ 228,341</u>
Issuance of common stock upon exercise of stock options	113,048	—	367	—	—	367
Stock-based compensation expense	—	—	2,529	—	—	2,529
Net loss	—	—	—	(14,013)	—	(14,013)
Other comprehensive loss	—	—	—	—	—	—
Balance at September 30, 2021	<u>31,955,050</u>	<u>\$ 3</u>	<u>\$ 369,732</u>	<u>\$ (152,511)</u>	<u>\$ —</u>	<u>\$ 217,224</u>

ADICET BIO, INC.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)
(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2019	12,048,698	\$ 114,083	2,155,578	\$ —	\$ 9,258	\$ (69,647)	\$ 23	\$ (60,366)
Net loss	—	—	—	—	—	(4,486)	—	(4,486)
Issuance of common stock upon exercise of stock options	—	—	19,947	—	42	—	—	42
Stock-based compensation expense	—	—	—	—	299	—	—	299
Other comprehensive loss	—	—	—	—	—	—	(15)	(15)
Balance at March 31, 2020	12,048,698	\$ 114,083	2,175,525	\$ —	\$ 9,599	\$ (74,133)	\$ 8	\$ (64,526)
Net loss	—	—	—	—	—	(8,455)	—	(8,455)
Issuance of common stock upon exercise of stock options	—	—	3,101	—	7	—	—	7
Stock-based compensation expense	—	—	—	—	351	—	—	351
Other comprehensive income	—	—	—	—	—	—	189	189
Balance at June 30, 2020	12,048,698	\$ 114,083	2,178,626	\$ —	\$ 9,957	\$ (82,588)	\$ 197	\$ (72,434)
Net loss	—	—	—	—	—	(14,779)	—	(14,779)
Issuance of common stock upon exercise of stock options	—	—	100,092	—	144	—	—	144
Stock-based compensation expense	—	—	—	—	2,966	—	—	2,966
Conversion of shares of redeemable convertible preferred stock to shares of common stock in connection with the Merger	(12,048,698)	(114,083)	12,048,671	1	114,082	—	—	114,083
Exchange of common stock in connection with the Merger	—	—	5,262,248	—	84,142	—	—	84,142
Conversion of redeemable convertible preferred stock warrants to common stock warrants	—	—	—	—	2,922	—	—	2,922
Other comprehensive income	—	—	—	—	—	—	(114)	(114)
Balance at September 30, 2020	—	\$ —	19,589,637	\$ 1	\$ 214,213	\$ (97,367)	\$ 83	\$ 116,930

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

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

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities		
Net loss	\$ (46,186)	\$ (27,720)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,173	911
Loss on disposal of property and equipment	190	—
Noncash lease expense	2,201	—
Stock-based compensation expense	8,231	3,616
Net amortization of premiums and accretion discounts on investments	10	(4)
Change in fair value of redeemable convertible preferred stock warrant liability	—	897
Amortization of deferred debt issuance costs	151	84
Impairment of in-process research and development	1,190	—
Remeasurement of contingent consideration liability	(980)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(462)	(5,000)
Other non-current assets	(81)	(1,560)
Accounts payable	3,079	1,442
Contract liabilities — related party	(3,892)	(2,493)
Deferred rent	—	(119)
Operating lease liabilities	(1,104)	—
Accrued and other current liabilities	(1,244)	1,738
Other non-current liabilities	116	1
Net cash used in operating activities	<u>(37,608)</u>	<u>(28,207)</u>
Cash flows from investing activities		
Cash and restricted cash acquired in connection with the Merger	—	64,114
Proceeds from sales of marketable debt securities	7,500	—
Purchases of marketable debt securities	—	(5,700)
Proceeds from maturities of marketable debt securities	2,750	44,985
Purchases of property and equipment	(9,968)	(630)
Net cash provided by investing activities	<u>282</u>	<u>102,769</u>
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	143,754	—
Proceeds from exercise of stock options	1,622	193
Deferred issuance costs	(154)	(157)
Net cash provided by (used in) financing activities	<u>145,222</u>	<u>36</u>
Net change in cash, cash equivalents and restricted cash	107,896	74,598
Cash, cash equivalents and restricted cash, at the beginning of period	88,857	14,889
Cash, cash equivalents and restricted cash, at the end of period	<u>\$ 196,753</u>	<u>\$ 89,487</u>
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	\$ 192,226	\$ 84,960
Restricted cash	4,527	4,527
Cash, cash equivalents and restricted cash	<u>\$ 196,753</u>	<u>\$ 89,487</u>
Supplemental cash flow information		
Cash received from tax refund	\$ 214	\$ 3
Supplemental disclosures of noncash investing and financing activities		
Purchases of property and equipment included in accounts payable	\$ 2,585	\$ 76
Conversion of redeemable convertible preferred stock into common stock	\$ —	\$ 144,083
Conversion of redeemable convertible preferred stock warrants into common stock warrants	\$ —	\$ 2,922
Fair value of net assets acquired in Merger	\$ —	\$ 84,142
Issuance of redeemable convertible preferred stock warrants in connection with the Loan Agreement	\$ —	\$ 144
Adjustment to goodwill	\$ 413	\$ —

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 biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer and other diseases. 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 believes its approach has potentially significant advantages over alpha beta T cells, which are the basis of standard CAR-T cell therapies and also natural killer cell-based therapies. The Company was incorporated in November 2014 in Delaware. The principal executive offices are located in Boston, Massachusetts. The Company also has another office in Menlo Park, California.

Adicet Bio, Inc. (when referred to prior to the Merger (as defined below), (Former Adicet)) was incorporated in November 2014 in Delaware and was headquartered in Menlo Park, CA. Adicet Bio Israel Ltd. (formerly Applied Immune Technologies Ltd.) (Adicet Israel) is a wholly owned subsidiary of Former Adicet and is located in Haifa, Israel. Adicet Israel was founded in 2006. During 2019, Former Adicet consolidated its operations, including research and development activities, in the U.S. and as a result substantially reduced its operations in Israel.

Merger with resTORbio

Prior to September 15, 2020, the Company was a clinical-stage biopharmaceutical company known as resTORbio that had historically focused on developing innovative medicines that target the biology of aging, to prevent or treat age-related diseases with the potential to extend healthy lifespans. On April 28, 2020, resTORbio entered into a definitive Merger Agreement with Former Adicet (the Merger Agreement). Under the terms of the Merger Agreement, Former Adicet agreed to merge 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.” (such transactions, the Merger). Under the exchange ratio formula in the Merger Agreement, immediately following the Effective Time of the Merger, the securityholders of Former Adicet as of immediately prior to the Effective Time of the Merger owned approximately 75% of the outstanding shares of the Company’s common stock on a fully-diluted basis and securityholders of resTORbio as of immediately prior to the Effective Time (as defined below) of the Merger owned approximately 25% of the outstanding shares of the Company’s common stock on a fully-diluted basis (in each case excluding equity incentives available for grant).

The Company concluded that the transaction represented a business combination pursuant to Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 805, *Business Combinations*. Further, Former Adicet was determined to be the accounting acquirer based upon the terms of the Merger and other factors including: (i) Former Adicet’s securityholders own approximately 75% of the voting rights of the combined company (on a fully-diluted basis excluding equity incentives available for grant); (ii) Former Adicet designated a majority (five of seven) of the initial members of the Board of Directors of the combined company; and (iii) the terms of the exchange of equity interests based on the exchange ratio at the announcement of the Merger factored in an implied premium to resTORbio’s stockholders. The composition of senior management of the combined company was determined to be a neutral factor in the accounting acquirer determination, as the combined company will leverage the expertise of the senior management of both companies. Accordingly, the reported operating results prior to the business combination are those of Former Adicet.

On September 15, 2020, the Company completed the Merger pursuant to the Merger Agreement (the Effective Time). In connection with the Merger, and immediately prior to the Effective Time, the Company effected a reverse stock split of the Company’s common stock at a ratio of 1-for-7 (the Reverse Stock Split). Also, in connection with the Merger, the Company changed its name from “resTORbio, Inc.” to “Adicet Bio, Inc.” (the Name Change), Former Adicet changed its name from “Adicet Bio, Inc.” to “Adicet Therapeutics, Inc.” and the business conducted by the Company became primarily the business which was previously conducted by Former Adicet, which is a biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer and other diseases.

At the Effective Time, each outstanding share of Former Adicet capital stock was converted into the right to receive 0.1240 (the Exchange Ratio) shares of Company's common stock, as set forth in the Merger Agreement. The Exchange Ratio was determined based on the total number of outstanding shares of Company's common stock and Former Adicet capital stock, each on a fully diluted basis, and the respective valuations of Former Adicet and resTORbio at the time of execution of the Merger Agreement. In connection with the Merger, the Company also assumed certain outstanding Former Adicet warrants and stock options under Former Adicet's 2015 Stock Incentive Plan (the 2015 Adicet Stock Incentive Plan) and Former Adicet's 2014 Share Option Plan (the 2014 Share Option Plan and, together with the 2015 Adicet Stock Incentive Plan, the Former Adicet Plans), with such stock options and warrants henceforth representing the right to purchase a number of shares of Company's common stock equal to the Exchange Ratio multiplied by the number of shares of Former Adicet's capital stock previously represented by such stock options and warrants, as applicable, with a proportionate adjustment in exercise price.

Immediately following the Effective Time, there were approximately 19,589,828 shares of the Company's common stock outstanding (post Reverse Stock Split) and the former equity holders of Former Adicet held approximately 75% of the outstanding shares of Company's common stock on a fully-diluted basis and the former equity holders of resTORbio held approximately 25% of the outstanding shares of Company's common stock on a fully-diluted basis (in each case excluding equity incentives available for grant).

Please refer to Note 3 "Business Combinations" for further details of the Merger.

Liquidity

The Company has incurred significant net operating losses and negative cash flows from operations and has an accumulated deficit of \$152.5 million as of September 30, 2021. The Company has historically financed its operations primarily through a collaboration and licensing arrangement, through the private placement of equity securities and debt, and cash received in the Merger. 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. The Company expects that its cash, cash equivalents and marketable debt securities, including the gross proceeds it received in February 2021 from its underwritten public offering 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 the Regeneron Agreement, which is 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 commercialize any of the Company's product candidates or enter 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 seek regulatory approvals for, its product candidates and begin 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 (U.S. 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, 2020. There have been no material changes to the significant accounting policies during the nine months ended September 30, 2021.

Unaudited Interim Financial Information

The consolidated balance sheet as of December 31, 2020 was derived from the Company's audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited consolidated financial statements as of September 30, 2021 and for the three and nine months ended September 30, 2021 and 2020, 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 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 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, 2020. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's consolidated financial position as of September 30, 2021 and consolidated results of operations for the three and nine months ended September 30, 2021 and 2020 and consolidated cash flows for the nine months ended September 30, 2021 and 2020 have been made. The results of operations for the three and nine months ended September 30, 2021 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2021.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents, and marketable debt securities. 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 and marketable debt securities in money market funds, U.S. government securities, commercial paper, corporate bonds, and asset-backed securities. The Company limits its credit risk associated with cash equivalents and marketable debt securities by placing them with banks and institutions it believes are highly creditworthy and in highly rated investments. The Company has not experienced any losses on its deposits of cash and cash equivalents and marketable debt securities to date.

The Company has one customer, Regeneron, which represents 100% of the Company's total revenue for the three and nine months ended September 30, 2021 and 2020 (see Note 10).

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 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 approval of the investigational new drug (INDs) for clinical trials, the enrollment of any clinical trials that are approved, the availability of clinical trial materials and regulatory approval and commercialization of our products. 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 December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740)—Simplifying the Accounting for Income Taxes, which simplify various aspects related to the accounting for income taxes. This ASU removes exceptions to the general principles in Topic 740 related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. For public companies, this ASU is effective for interim and annual reporting periods beginning after December 15, 2020. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted. The Company adopted ASU 2019-12 beginning January 1, 2021 on a prospective basis. The adoption of this standard did not have a material impact on its financial statements and related disclosures.

In November 2018, the FASB issued Accounting Standards Update (ASU) 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*, which is intended to clarify the circumstances under which certain transactions in collaborative arrangements should be accounted for under the revenue recognition standard. Certain transactions between collaboration arrangement participants should be accounted for as revenue under ASC Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. For public business entities, this ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. For all other entities, this ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2020. Early adoption is permitted. The Company adopted ASU 2018-18 beginning January 1, 2021 on a prospective basis. The adoption of this standard did not have a material impact on its financial statements and related disclosures.

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, 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 public business entities that meet the definition of a SEC filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, adoption is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. For SEC filers that are eligible to be smaller reporting companies and for all other entities, 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 is currently evaluating the impact the adoption of this ASU will have on its consolidated financial statements and related disclosures.

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848)* (ASU 2020-04). The amendments in ASU 2020-04 provide optional expedients and exceptions for applying generally accepted accounting principles to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The amendments in ASU 2020-04 are effective for all entities as of March 12, 2020 through December 31, 2022. An entity may elect to apply the amendments for contract modifications by Topic or Industry Subtopic as of any date from the beginning an interim period that includes or is subsequent to March 12, 2020, or prospectively from the date that the financial statements are available to be issued. Once elected for a Topic or an Industry Subtopic, the amendments must be applied prospectively for all eligible contract modifications for that Topic or Industry Subtopic. The Company may elect to apply ASU 2020-04 as its contracts referenced in London Interbank Offered Rate (LIBOR) are impacted by reference rate reform. The Company is currently evaluating the impact of the adoption of this ASU on the Company's consolidated financial statements.

3. Business Combination

On September 15, 2020, Former Adicet completed its Merger with resTORbio. Based on the Exchange Ratio of 0.1240, immediately following the Merger, resTORbio stockholders and holders of resTORbio restricted stock units and options to acquire resTORbio common stock owned approximately 25.0% of the outstanding capital stock of the combined company on a fully diluted basis, and Former Adicet stockholders, holders of options or warrants to acquire Former Adicet capital stock owned approximately 75.0% of the outstanding capital stock of the combined company on a fully diluted basis. At the closing of the Merger, all shares of Former Adicet common stock and Former Adicet redeemable convertible preferred stock then outstanding were converted to Former Adicet's common stock under their original terms and were then exchanged for the Company's common stock.

resTORbio's stockholders will continue to own and hold their existing shares of the Company's common stock (after giving effect to the 1-for-7 reverse stock split). Pursuant to the terms of the Merger, the vesting of all outstanding resTORbio stock options was accelerated in full as of immediately prior to the Effective Time. All out-of-the-money resTORbio stock options were cancelled for no consideration. All in-the-money resTORbio stock options remained outstanding after the completion of the Merger in accordance with their terms. For accounting purposes, the Company assumed 81,370 in-the-money resTORbio stock options after giving effect to reverse stock split. In addition, 91,309 unvested resTORbio restricted stock units outstanding and unsettled, after giving effect to reverse stock split, as of immediately prior to the effective time of the Merger, were accelerated in full and the holders of such restricted stock units received 54,553 shares of the Company's common stock (after reduction by the number of shares of resTORbio common stock necessary to satisfy applicable tax withholding obligations at the maximum statutory rate). The fair value of these modified stock options and restricted stock units attributable to pre-combination services was recorded as a component of consideration transferred and the fair value of these modified stock options and restricted stock units attributable to post-combination services was recognized as stock compensation expense in the Company's consolidated statements of operations and comprehensive loss at the close of the Merger. At the closing of the Merger, all shares of Former Adicet common stock and Former Adicet redeemable convertible preferred stock then outstanding were converted to Former Adicet's common stock under their original terms and were then exchanged for the Company's common stock.

In connection with the Merger, the Company entered into a Contingent Value Rights Agreement (the CVR Agreement) with Computershare Inc. and Computershare Trust Company, N.A. as joint rights agent. Per the terms of the Merger, each holder of resTORbio common stock as of immediately prior to the completion of the Merger is entitled to one contractual contingent value right, subject to and in accordance with the terms and conditions of the CVR Agreement, for each share of resTORbio common stock held by such holder as of immediately prior to the Effective Time. The CVR holders are entitled to receive net proceeds from the commercialization, if any, from a third-party commercial partner of RTB101, resTORbio's small molecule product candidate that is a potent inhibitor of target of rapamycin complex 1 (TORC1), for a COVID-19 related indication. RTB101 relates to an exclusive license agreement resTORbio entered with Novartis International Pharmaceutical Ltd. (Novartis) (see Note 11).

The total purchase price was allocated to the tangible and intangible assets acquired and liabilities assumed of resTORbio based on their fair values as of the completion of the Merger, with the excess allocated to goodwill. The purchase price is calculated based on the fair value of resTORbio common stock that the resTORbio stockholders owned as of the closing date of the Merger because, with no active trading market for shares of Former Adicet, the fair value of the resTORbio's common stock represented a more reliable measure of the fair value of consideration transferred in the Merger.

The following summarizes the purchase price in the Merger (in thousands, except share and per share amounts):

Fair value of common stock shares of the combined company owned by resTORbio stockholders (1)	\$	84,142
Fair value of contingent consideration liability with respect to CVR (2)		2,880
Purchase price	\$	<u>87,022</u>

- (1) Represents the share consideration of the combined company that the resTORbio stockholders own as of the closing of the Merger calculated as follows:

Number of shares of the combined company owned by resTORbio stockholders (a)	5,207,695
Multiplied by the fair value per share of resTORbio common stock (b)	\$ 16.59
Acquisition date fair value of resTORbio	86,396
Estimated fair value of modified stock options and restricted stock units attributable to pre-combination services (3)	626
Less: portion of the fair value to be distributed as CVR (c)	<u>(2,880)</u>
Fair value of shares of the combined company owned by resTORbio stockholders	<u>\$ 84,142</u>

- a. Represents the number of shares of common stock of the combined company that the resTORbio stockholders owned as of the closing of the Merger. This amount is calculated as 5,207,695 shares of resTORbio common stock outstanding as of September 15, 2020.
- b. The purchase price is based on the closing price of resTORbio common stock on September 14, 2020.
- c. The fair value of resTORbio common stock was further adjusted to remove the estimated fair value of the CVR embedded within the closing price, as each holder of resTORbio stock will receive one contractual CVR immediately prior to the Merger.
- (2) Each holder of resTORbio common stock as of immediately prior to the completion of the Merger was entitled to one CVR issued by resTORbio, subject to and in accordance with the terms and conditions of the CVR Agreement, for each share of resTORbio common stock held by such holder as of immediately prior to the effective time of the Merger.
- (3) Based on the capitalization of resTORbio as of September 15, 2020, 91,309 outstanding unvested resTORbio restricted stock units were accelerated in connection with the Merger and holders of the restricted stock units were issued approximately 54,553 shares of resTORbio common stock on a net settlement basis. Similarly, in connection with the Merger, vesting of outstanding resTORbio stock options was accelerated in full and the stock options that were not in the in-the-money on the close of the Merger were canceled, resulting in approximately 81,370 surviving stock options. The acquisition date fair value of these modified resTORbio restricted stock units and resTORbio stock options attributable to the pre-combination services is included in the estimated purchase price.

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.

The following summarizes the allocation of the purchase price to the net tangible and intangible assets acquired (in thousands):

	As of December 31, 2020	Measurement Period Adjustments	Final Purchase Price Allocation
Net assets acquired:			
Cash and cash equivalents	\$ 63,869	\$ —	\$ 63,869
Prepaid expenses and other current assets	3,059	615	3,674
Property and equipment	318	—	318
IPR&D	3,490	—	3,490
Restricted cash	245	—	245
Accounts payable	(1,316)	—	(1,316)
Accrued and other current liabilities	(2,365)	12	(2,353)
Other liabilities	—	—	—
Deferred tax liability	(367)	—	(367)
Goodwill	20,089	(627)	19,462
Purchase price	<u>\$ 87,022</u>	<u>\$ —</u>	<u>\$ 87,022</u>

The goodwill of \$19.5 million 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, as reflected in the increase in market value of the resTORbio common shares following the announcement of the Merger with Former Adicet.

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.

The contingent consideration for the 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 (as discussed above). These cash flows were then discounted to present value using the same discount rate applied in the valuation of the IPR&D.

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 September 30, 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):

	September 30, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (1)	\$ 174,945	\$ —	\$ —	\$ 174,945
Total fair value of assets	\$ 174,945	\$ —	\$ —	\$ 174,945
	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (1)	\$ 63,817	\$ —	\$ —	\$ 63,817
Marketable debt securities (2)				
Asset-backed securities	—	7,522	—	7,522
Corporate debt securities	—	1,762	—	1,762
Commercial paper	—	1,000	—	1,000
Marketable debt securities	—	10,284	—	10,284
Total fair value of assets	\$ 63,817	\$ 10,284	\$ —	\$ 74,101
Liabilities:				
Contingent consideration	\$ —	\$ —	\$ 980	\$ 980
Total fair value of liabilities	\$ —	\$ —	\$ 980	\$ 980

- (1) Included in cash and cash equivalents in the consolidated balance sheets.
- (2) Included in short-term marketable debt securities in the consolidated balance sheets.

Money market funds are included within Level 1 of the fair value hierarchy because they are valued using quoted market prices. Corporate debt securities, U.S. government agency bonds, commercial paper and asset-backed securities are classified within Level 2 of the fair value hierarchy as they take into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income-based and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate the fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs.

As part of the acquisition of resTORbio, the Company entered into a CVR Agreement and recorded the fair value of the CVR as part of consideration transferred. The Company considers the contingent consideration liability a Level 3 instrument (one with significant unobservable inputs) in the fair value hierarchy. In June 2021, the Company determined the possibility of any commercialization events for RTB101 was close to zero (see Note 3). As a result, the fair value of the CVR liability was adjusted to zero. On October 27, 2021, the Company provided a Termination Notice under the CVR Agreement to the joint rights agents to terminate its obligations under the CVR Agreement, effective immediately.

5. Marketable Debt Securities

The Company had no marketable debt securities as of September 30, 2021. The following table summarizes the Company's marketable debt securities as of December 31, 2020 (in thousands):

	December 31, 2020			
	Amortized Cost	Unrealized Losses	Unrealized Gains	Fair Value
Asset-backed securities	\$ 7,507	\$ —	\$ 15	\$ 7,522
Corporate debt securities	1,754	—	8	1,762
Commercial paper	999	—	1	1,000
Total	<u>\$ 10,260</u>	<u>\$ —</u>	<u>\$ 24</u>	<u>\$ 10,284</u>

The following table summarizes the classification of the Company's marketable debt securities in the consolidated balance sheets (in thousands):

	September 30, 2021	December 31, 2020
Short-term marketable debt securities	\$ —	\$ 10,284
Long-term marketable debt securities	—	—
Total	<u>\$ —</u>	<u>\$ 10,284</u>

6. Prepaid Expenses and Other Current Assets

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

	September 30, 2021	December 31, 2020
Prepaid maintenance and other	\$ 655	\$ 761
Prepayments to CRO's	1,643	420
Prepayments to CMO's	1,340	135
Prepaid insurance	449	1,443
Tax receivable	2,711	2,711
Interest receivable	—	23
Other current assets	1	229
Total prepaid expenses and other current assets	<u>\$ 6,799</u>	<u>\$ 5,722</u>

7. Property and Equipment, net

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

	Useful life (in years)	September 30, 2021	December 31, 2020
Laboratory equipment	3	\$ 5,502	\$ 4,350
	Lesser of useful life or lease term		
Leasehold improvements		1,614	1,427
Furniture and fixtures	3	303	524
Construction in progress	—	9,402	1,090
Computer equipment	3	217	93
Software	3	320	170
		<u>17,358</u>	<u>7,654</u>
Less: Accumulated depreciation and amortization		(5,963)	(4,864)
Property and equipment, net		<u>\$ 11,395</u>	<u>\$ 2,790</u>

Depreciation and amortization expense was \$0.4 million and \$0.3 million for the three months ended September 30, 2021 and 2020, respectively. Depreciation and amortization expense was \$1.2 million and \$0.9 million for the nine months ended September 30, 2021 and 2020, respectively. Construction in progress has increased by \$6.8 million and \$9.4 million in the three and nine months ended September 30, 2021, due to building construction related to the Company's leased space in

Redwood City. Construction in process will continue to increase through the first half of 2022, upon completion of the construction.

8. Accrued and Other Current Liabilities

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

	September 30, 2021	December 31, 2020
Accrued compensation	\$ 3,316	\$ 3,833
Accrued CRO costs	490	955
Accrued CMO costs	165	244
Accrued research and development expenses	294	65
Accrued professional services	301	363
Accrued other liabilities	35	272
Total accrued and other liabilities	<u>\$ 4,601</u>	<u>\$ 5,732</u>

9. Term Loan

The Company has a Loan and Security Agreement dated as of April 28, 2020 with Pacific Western Bank (PacWest or the Bank) for an initial term loan limit not exceeding \$12.0 million (the Loan Agreement) to finance leasehold improvements for the facilities in Redwood City, CA and other purposes permitted under the Loan Agreement, with an interest rate equal to the greater of 0.25% above the Prime Rate (as defined in the Loan Agreement) or 5.00%. As of September 30, 2021, no amounts had been drawn under the Loan Agreement and the deferred debt issuance costs were \$0.1 million and are included in other noncurrent assets on the Company's consolidated balance sheets.

On October 21, 2021, the Company entered into a Fourth Amendment of the Loan Agreement (the Loan Amendment) under which the Bank 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. The aggregate sum of the outstanding Term Loans and non-formula ancillary services shall at no time exceed \$15.0 million, with each term loan to be in an amount of not less than \$1.0 million. 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%. Other than as disclosed in this Quarterly Report on Form 10-Q, there have been no material changes in the Loan Agreement from those disclosed in Note 9 to consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

10. 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 September 30, 2021. 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 Effective Time of the Merger.

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 a transaction price of the Regeneron Agreement consisting of the \$25.0 million upfront payment and the aggregate research funding fees 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 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, certain 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. As a result, during the three months ended September 30, 2019, the Company recorded \$6.6 million as a reduction to cumulative revenue recognized prior to the amendment effective date. The Company will re-evaluate 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 when it achieved the

milestone for the selection of a clinical candidate to the second collaboration target under the Regeneron Agreement, resulting in the recognition of an additional \$5.0 million in revenue during the three months ended June 30, 2020. 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 and nine months ended September 30, 2021, the Company recorded \$3.4 million and \$4.3 million in revenue, respectively.

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 has 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. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

The following tables present changes in the Company's contract liabilities for the nine months ended September 30, 2021 and 2020 (in thousands):

Nine Months Ended September 30, 2021	Balance at Beginning of Period	Additions	Additions (Deductions) (1)	Balance at End of Period
Contract liability	\$ 13,980	\$ 370	\$ (4,262)	\$ 10,088

Nine Months Ended September 30, 2020	Balance at Beginning of Period	Additions	Additions (Deductions) (1)	Balance at End of Period
Contract asset	\$ —	\$ 10,000	\$ (10,000)	\$ —
Contract liability	\$ 21,883	\$ 10,000	\$ (12,493)	\$ 19,390

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

As of September 30, 2021, contract liabilities related to the Regeneron Agreement of \$10.1 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 \$35.3 million of cumulative license and collaboration revenue recognized from the inception of the Regeneron Agreement as of September 30, 2021 and will be recognized as the combined performance obligation is satisfied.

As of September 30, 2020, contract liabilities related to the Regeneron Agreement of \$19.4 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 \$25.6 million of cumulative license and collaboration revenue recognized from the inception of the Regeneron Agreement as of September 30, 2020.

As of September 30, 2020, there were no contract assets which would be reflected as accounts receivable-related party on the consolidated balance sheet. The Company achieved the milestone for the selection of a clinical candidate to the second collaboration target under the Regeneron Agreement in June 2020 and was entitled to receive a payment of \$10.0 million from Regeneron. The Company received the payment from Regeneron in July 2020.

11. License, Funding and Other Agreements Related to the CVR

Contingent Value Rights Agreement

As discussed in Note 3, in connection with the Merger, the Company entered into the CVR Agreement with Computershare Inc. and Computershare Trust Company, N.A. as joint rights agent. The CVR holders are entitled to receive net proceeds from the commercialization, if any, received from a third-party commercial partner of RTB101 for a COVID-19 related indication. The total fees and expenses of the Company's clinical trials for a COVID-19 related indication of RTB101 is limited to \$3.0 million under the CVR Agreement. Through October 31, 2020, the Company's total accumulated spend was \$1.1 million of expenses. In November 2020, management terminated the nursing home study due to slow enrollment and as a consequence lowered the probability of finding a partner due to the delay in time to commercialization of RTB101. In February 2021, management terminated the National Institute on Aging study of RTB101 for COVID-19 post-exposure prophylaxis in adults age 65 years and older due to poor enrollment. In March 2021, management estimated that the probability of finding a partner should be further reduced. As a result, the fair value of the CVR liability was decreased by \$0.4 million to \$0.6 million. In June 2021, the Company determined the possibility of any commercialization events for RTB101 was close to zero (see Note 3). As a result, the fair value of the CVR liability was adjusted to zero.

On October 27, 2021, the Company provided a Termination Notice under the CVR Agreement to the joint rights agent to terminate its obligations under the CVR Agreement, effective immediately.

Novartis License Agreement

On March 23, 2017, resTORbio entered into an exclusive license agreement with Novartis. Under the agreement, Novartis granted resTORbio an exclusive, field-restricted, worldwide license, to certain intellectual property rights owned or controlled by Novartis, to develop, commercialize and sell one or more therapeutic products comprising RTB101 or RTB101 in combination with everolimus in a fixed dose combination. The exclusive field under the license agreement is for the treatment, prevention and diagnosis of disease and other conditions in all indications in humans and animals.

The agreement may be terminated by either party upon a material breach of obligation by the other party that is not cured with 60 days after written notice. resTORbio may terminate the agreement in its entirety or on a product-by-product or country-by-country basis with or without cause with 60 days' prior written notice.

Novartis may terminate the portion of the agreement related to everolimus if resTORbio fails to use commercially reasonable efforts to research, develop and commercialize a product utilizing everolimus for a period of three years. Novartis may terminate the license agreement upon resTORbio's bankruptcy, insolvency, dissolution or winding up.

As consideration for the license, resTORbio is required to pay up to an aggregate of \$4.3 million upon the satisfaction of clinical milestones, up to an aggregate of \$24 million upon the satisfaction of regulatory milestones for the first indication approved, and up to an aggregate of \$18 million upon the satisfaction of regulatory milestones for the second indication approved. In addition, resTORbio is required to pay up to an aggregate of \$125 million upon the satisfaction of commercial milestones, based on the amount of annual net sales. resTORbio is also required to pay tiered royalties ranging from a mid-single digit percentage to a low-teen digit percentage on annual net sales of products. These royalty obligations last on a product-by-product and country-by-country basis until the latest of (i) the expiration of the last valid claim of a Novartis patent covering a subject product, (ii) the expiration of any regulatory exclusivity for the subject product in a country, or (iii) the 10th anniversary of the first commercial sale in the country, and are subject to a reduction after the expiration of the last valid claim of a Novartis patent or the introduction of a generic equivalent of a product in a country.

On July 27, 2021, the Company sent Novartis a termination notice. Termination automatically took effect on September 25, 2021, 60 days from the date of delivery of the termination notice to Novartis, without any further notice or action required of either Novartis or the Company.

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 September 30, 2021, no qualifying expenses have been incurred and \$36,000 have been funded by the NIH. For the nine months ended September 30, 2021, \$0.3 million qualifying expenses have been incurred and \$0.5 million have been funded by the NIH. The difference in the amount incurred by the Company and funded by the NIH was due to timing of requesting reimbursements from the NIH. On a cumulative basis as of September 30, 2021, \$1.3 million has been incurred and \$1.3 million has been funded by the NIH.

12. Commitments and Contingencies

Operating Leases

The Company leases office and laboratory space in Menlo Park, CA, Redwood City, CA, and Boston, MA. As of September 30, 2021, except as described below, there have been no material changes in lease obligation from those disclosed in Note 12 to consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

On June 25, 2021, the Company entered into an amendment to the Menlo Park lease to extend the term of the lease from March 31, 2022 to June 30, 2022 and replace the previously leased premises (known as 173 and 175-177 Jefferson Drive) with another 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, the Company will incur monthly rent payments ranging from \$87,286 to \$89,904, increasing over the remaining term of the lease. Given the lease is short-term in nature, the Company is using the practical expedient for the lease and has not recorded a right of use asset or lease liability. Therefore, the Company will recognize rent expense on a straight-line basis over the lease term.

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 starting 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 September 30, 2021 is as follows (in thousands):

2021 (remaining three months)	\$	174
2022		697
2023		711
2024		725
2025		740
2026 and thereafter		439
Total	\$	<u>3,486</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.

On July 30, 2021, the Company entered a short-term lease agreement with Boston Properties, Inc. for office space located at 200 Clarendon Street, Boston, MA. The initial lease term commenced on July 30, 2021 and expires on November 30, 2021. In October 2021, the Company extended the lease term to March 31, 2022. The base rent is approximately \$9,000

per month. Due to the lease being short-term in nature, the Company elected the practical expedient for the lease and has recognized rent expenses as incurred.

The future minimum lease payments under all non-cancelable operating lease obligations as of September 30, 2021 were as follows (in thousands):

2021	\$	503
2022		2,933
2023		3,428
2024		3,525
2025		3,625
2026 and thereafter		13,747
Total undiscounted lease payments		27,761
Less: imputed interest		7,226
Total operating lease liability		20,535
Less: current portion		712
Operating lease liability, net of current maturities	\$	19,823

13. 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, 2020.

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 September 30, 2021 and December 31, 2020, no dividends on common stock had been declared by the Board of Directors.

As of September 30, 2021, the Company's outstanding warrants to purchase shares of common stock, consisted of the following:

<u>Issuance Date</u>	<u>Number of Shares of Common Stock Issuable</u>	<u>Exercise Price</u>	<u>Classification</u>	<u>Expiration Date</u>
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
	<u>220,890</u>			

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

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Stock options available for future grant	2,693,496	1,739,621
Stock options issued and outstanding	4,276,356	3,706,945
Unvested restricted stock units	217,160	—
Common stock warrants issued and outstanding	220,890	226,191
Total	<u>7,407,902</u>	<u>5,672,757</u>

14. Stock-based Compensation

Stock-based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 796	\$ 951	\$ 3,209	\$ 1,125
General and administrative	1,733	2,015	5,022	2,491
Total stock-based compensation	\$ 2,529	\$ 2,966	\$ 8,231	\$ 3,616

Stock Options

A summary of stock option activity for the nine months ended September 30, 2021 is set forth below:

	Number of Shares Available for Grant	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, 2020	1,739,621	3,706,945	\$ 10.90	7.98	\$ 15,126
Options authorized	2,287,089	—			
Options granted	(2,171,632)	1,954,472	\$ 14.89		
Options exercised	—	(546,642)	\$ 2.98		
Options forfeited or cancelled	838,419	(838,419)	\$ 14.15		
Outstanding, September 30, 2021	<u>2,693,497</u>	<u>4,276,356</u>	\$ 13.10	7.96	\$ 2,101
Options exercisable, September 30, 2021		1,329,752	\$ 9.77	5.33	\$ 1,907
Vested and expected to vest, September 30, 2021		4,276,356	\$ 13.10	7.96	\$ 2,101

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Fair value of common stock	\$7.84 - \$8.35	\$5.96 - \$10.66	\$7.84 - \$16.82	\$4.85 - \$10.66
Expected term (years)	5.6 - 6.1	1.0 - 6.1	0.9 - 6.1	1.0 - 6.1
Volatility	78.0% - 78.2%	77.1% - 96.4%	77.9% - 79.8%	72.6% - 96.3%
Risk free rates	0.9% - 1.2%	0.1% - 0.4%	0.1% - 1.2%	0.1% - 1.7%
Dividend rate	0.0%	0.0%	0.0%	0.0%

Restricted Stock Units

In May 2021, the Company granted 6,410 performance stock units (PSUs) to an employee with a grant date fair value of \$15.60 per share. The PSUs provide immediate acceleration of vesting in the event of a certain performance milestone to be achieved by March 31, 2022. The probability of achieving this milestone is expected to be 100% as of September 30, 2021. In addition, the Company granted 210,750 restricted stock units (RSUs) to employees in August 2021 with a weighted-average grant date fair value of \$7.12 per share.

The summary of RSU activity and related information follows:

	Number of Units Outstanding	Weighted-Average Grant Date Fair Value
Outstanding, December 31, 2020	—	
RSUs granted	217,160	\$ 7.37
RSUs Vested	—	
RSUs forfeited	—	
Outstanding, September 30, 2021	<u>217,160</u>	<u>\$ 7.37</u>

Summary of Plans

The Company has 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, 2020.

The 2017 Plan and 2018 Plan

As of September 30, 2021, the number of shares of common stock available for grant under the 2017 and 2018 Plan is 2,349,535 shares. As of September 30, 2021, an aggregate of 2,686,287 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 \$15.41 per share. Included in this amount was a grant of 6,410 PSUs and 210,750 shares of RSUs the Company granted in May 2021 and August 2021, respectively.

The 2014 Plan and 2015 Plan

As of September 30, 2021, the number of shares of common stock available for grant under the 2014 and 2015 Plans is 343,961. As of September 30, 2021, an aggregate of 1,421,746 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 \$8.96 per share and an aggregate of 22,989 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, 2021, 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 131,432 to 209,135 shares. During the 2021 Annual Meeting of the stockholders held on April 27, 2021, the stockholders approved an amendment and restatement of the Company's 2018 ESPP. As a result, the Company increased the shares available for issuance under the 2018 ESPP to 524,775 shares. No shares have been issued under the 2018 ESPP during the three and nine months ended September 30, 2021.

Inducement Grant

As of September 30, 2021, an aggregate of 362,503 shares of 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 \$14.33 per share.

15. Net Loss per Share

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders, which excludes unvested restricted shares and shares which are legally outstanding, but subject to repurchase by the Company (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss attributable to common stockholders	\$ (14,013)	\$ (14,779)	\$ (46,186)	\$ (27,720)
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	31,876,016	5,208,887	29,954,616	3,190,557
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.44)	\$ (2.84)	\$ (1.54)	\$ (8.69)

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

	As of September 30,	
	2021	2020
Redeemable convertible preferred stock	—	12,048,671
Options to purchase common stock	4,276,356	1,847,518
Redeemable convertible preferred stock warrants	—	220,890
Common stock warrants	220,890	—
Total	4,497,246	14,117,079

16. Income Taxes

The Company recorded an income tax expense of \$11,000 and benefit of \$114,000 during the three and nine months ended September 30, 2021, respectively. The Company recorded an income tax benefit of \$3,000 and \$2.7 million during the three and nine months ended September 30, 2020, respectively.

The income tax benefit during the three and nine months ended September 30, 2021 was due to the tax effect of the reduction in the deferred tax liability associated with the basis differences from IPR&D. In comparison, the income tax benefit during the three and nine months ended September 30, 2020 was as a result of the recognition of net operating loss carryback under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).

The Company maintains a full valuation allowance against its deferred tax assets due to the Company's history of losses as of September 30, 2021.

17. Related Party

As of September 30, 2021 and December 31, 2020, 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 and nine months ended September 30, 2021, the Company recorded revenue from the Regeneron Agreement of \$3.4 million and \$4.3 million, respectively. For the three and nine months ended September 30, 2020, the Company recognized revenue from the Regeneron Agreement of \$3.0 million and \$12.5 million, respectively. As of September 30, 2021, the Company has deferred revenue of \$10.1 million related to the Regeneron Agreement. See Note 10 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, 2020. 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 and in our Annual Report on Form 10-K for the year ended December 31, 2020, as supplemented by our subsequent filings with the SEC.

Overview

We are a biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer and other diseases. We are advancing a pipeline of “off-the-shelf” gamma delta T cells, engineered with 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. Gamma delta cells are unique in that they may have an inherent capacity to persist following treatment, and can recognize and kill circulating tumor cells and to infiltrate and kill solid tumors. We believe that by applying our proprietary engineering and manufacturing approach to gamma delta T cells we will potentially have significant advantages over alpha beta T cell-based therapies, which are the basis of standard CAR-T cell therapies and also natural killer (NK) cell-based therapies, which are currently in development.

Our proprietary engineering and manufacturing process begins with isolating and expanding gamma delta T cells from the blood of healthy donors, and results in the potential to treat up to 1,000 patients per batch depending on dosing and the CAR target with an “off-the-shelf” product that is available on demand. 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 products 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 FDA cleared our Investigational New Drug (IND) application for ADI-001, our lead product candidate, for the treatment of Non-Hodgkin’s Lymphoma (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 non-Hodgkin’s lymphoma patients at a number of cancer centers across the U.S. The study includes a dose escalation portion followed by dose expansion cohorts to explore the activity of ADI-001 in multiple subtypes of NHL. As of November 10, 2021, we have completed dosing for dose level 1 and enrollment is ongoing for dose level 2 of the Phase 1 study. We expect to announce interim clinical data from the initial dose escalation portion of this study by the end of 2021. We intend to file an IND with the FDA in the second quarter of 2022 for ADI-002, our first solid tumor product candidate, and subject to the FDA’s regulatory process for review of INDs, initiate Phase 1 clinical trials of ADI-002 in the second half of 2022.

Recent Developments

Reverse Merger

On April 28, 2020, Adicet Bio, Inc. (Former Adicet) entered into an agreement and plan of Merger with resTORbio, Inc., a Delaware corporation (resTORbio), and Project Oasis Merger Sub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of resTORbio (Merger Sub), pursuant to which, subject to the satisfaction or waiver of the conditions therein, Merger Sub agreed to merge with and into Former Adicet, with Former Adicet surviving as a wholly owned subsidiary of resTORbio and changing the name to Adicet Therapeutics, Inc., (such transactions, the Merger). The Merger was subject to certain conditions, including the approval of resTORbio stockholders.

On September 15, 2020, we completed the Merger. In connection with the completion of the Merger, resTORbio was renamed Adicet Bio, Inc. (Adicet Bio). Immediately prior to the Effective Time of the Merger, resTORbio effected a reverse stock split of its common stock at a ratio of 1-for-7 or the Reverse Stock Split). At the Effective Time of the Merger, each outstanding share of Former Adicet’s capital stock was converted into the right to receive 0.1240 (the Exchange Ratio) shares of resTORbio common stock.

The business combination has been accounted for as a reverse Merger in accordance with the Generally Accepted Accounting Principles in the United States of America (U.S. GAAP or GAAP). Under this method of accounting, Former Adicet is deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the facts that, immediately following the Merger: (i) Former Adicet's securityholders own approximately 75% of the voting rights of the combined company (on a fully-diluted basis excluding equity incentives available for grant); (ii) Former Adicet designated a majority (five of seven) of the initial members of the Board of Directors of the combined company; and (iii) the terms of the exchange of equity interests based on the exchange ratio at the announcement of the Merger factored in an implied premium to resTORbio's stockholders. The composition of senior management of the combined company was determined to be a neutral factor in the accounting acquirer determination, as the combined company will leverage the expertise of the senior management of both companies. Accordingly, for accounting purposes, the business combination has been treated as the equivalent of Former Adicet issuing stock to acquire the net assets of resTORbio. As a result, as of the closing date of the Merger, the net assets of resTORbio have been recorded at their acquisition-date fair values in the financial statements of the combined entity and the reported operating results prior to the business combination are those of Former Adicet. Subsequent to the closing of the Merger, the reported operating results will reflect those of the combined organization. In addition, transaction costs incurred by Former Adicet in connection with the business combination have been expensed as incurred. Our common stock remained listed on the Nasdaq Stock Market, with trading having commenced on a post-Merger and post-Reverse Stock Split basis and under the new name as of September 16, 2020. The trading symbol also changed on that date from "TORC" to "ACET."

Public Offering and Concurrent Private Placement

In February 2021, the Company completed an underwritten public offering of 10,575,513 shares of the Company's 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 \$128.7 million.

In connection with the offering, the Company also entered into a stock purchase agreement with certain existing investors for 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. The Company 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. The shares sold in the private placement were not registered under the Securities Act.

Loan Agreement

On April 28, 2020, we entered into a Loan and Security Agreement with Pacific Western Bank for a term loan not exceeding \$12.0 million (the Loan Agreement) to finance leasehold improvements for our facilities in Redwood City, CA and other purposes permitted under the Loan Agreement, with an interest rate equal to the greater of 0.25% above the Prime Rate (as defined in the Loan Agreement) or 5.00%. In connection with the entrance into the Loan Agreement, we issued Pacific Western Bank a warrant to purchase shares of our Series B redeemable convertible preferred stock (described below) at an exercise price of \$1.4034 per share. Such warrant was initially exercisable for 42,753 shares of our Series B redeemable convertible preferred stock. Upon the closing of the Merger, it was exchanged for a warrant (the New PacWest Warrant) to purchase 5,301 shares of common stock at an exercise price of \$11.32 per share and shall be exercisable for an additional number of shares of common stock equal to 1.00% of the aggregate original principal amount of all term loans made pursuant to the Loan Agreement (up to an aggregate maximum of 15,903 shares of common stock). The New PacWest Warrant was fully exercised in February 2021 and the net issuance was 1,806 shares of common stock. Further, 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. 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.

On October 21, 2021, we entered into a Fourth Amendment of the Loan Agreement (the Loan Amendment) under which Pacific Western Bank will provide one or more term loans (the Term Loans), as well as certain non-formula ancillary services (the Non-Formula Ancillary Services), which shall not exceed \$5.5 million in the aggregate. The aggregate sum of the outstanding Term Loans and Non-Formula Ancillary Services shall at no time exceed \$15.0 million, with each term loan to be in an amount of not less than \$1.0 million. Pursuant to the Loan Amendment, the interest rate for the Terms 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%.

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 September 30, 2021.

Impact of COVID-19 Pandemic

In December 2019, a novel strain of coronavirus, COVID-19, was reported in China. Since then, COVID-19 has spread globally. The spread of COVID-19 from China to other countries has 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. The ongoing COVID-19 pandemic continues to evolve and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions, vaccination mandates, and other public health safety measures.

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. Further, a recession or market correction resulting from the spread of COVID-19 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. Although our financial results to date have not been significantly impacted by COVID-19, we cannot at this time predict the specific extent, duration, or full impact that the ongoing COVID-19 pandemic will have on our financial condition, operations, and business plans.

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 an aggregate of \$20.0 million of additional payments for research funding from Regeneron as of September 30, 2021. In addition, Regeneron may have to pay us additional amounts in the future consisting of up to an aggregate of \$100.0 million of option exercise fees, in each case as specified in the Regeneron Agreement. Regeneron must also pay us 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 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 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 of clinical trials;
- 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 variables with respect to the development of a product candidate could significantly change the costs, timing and viability associated with the development of that product candidate. For example, if the FDA, or another regulatory authority, were to require us to conduct clinical trials beyond those that it currently anticipates will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our product candidates will receive regulatory approval with any certainty.

We are focusing substantially all of our resources on the development of our product candidates. We expect our research and development expenses to increase substantially during the next few years, as we seek to initiate clinical trials for our product candidates, complete our clinical program, pursue regulatory approval of our product candidates and prepare for a possible commercial launch. Predicting the timing or the cost to complete our clinical program or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our product candidates will receive regulatory approval with any certainty.

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 term loan agreement entered into in April 2020.

Other Income (Expense), Net

Other income (expense), net primarily consists of changes in the fair value of our redeemable convertible preferred stock tranche liability and redeemable convertible preferred stock warrant liability prior to their conversion to warrants to purchase common stock upon closing of the Merger.

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

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

	Three Months Ended September 30,		Change	% Change
	2021	2020		
Revenue – related party	\$ 3,429	\$ 3,028	\$ 401	13 %
Operating expenses				
Research and development	11,926	8,942	2,984	33 %
General and administrative	5,213	7,741	(2,528)	-33 %
Total operating expenses	17,139	16,683	456	3 %
Loss from operations	(13,710)	(13,655)	(55)	0 %
Interest income	4	153	(149)	-97 %
Interest expense	(50)	(50)	—	0 %
Other income (expense), net	(246)	(1,224)	978	80 %
Loss before income tax benefit	(14,002)	(14,776)	774	-5 %
Income tax provision (benefit)	11	3	8	267 %
Net loss	\$ (14,013)	\$ (14,779)	\$ 766	-5 %

Revenue

Revenue increased by \$0.4 million, or 13%, for the three months ended September 30, 2021 compared to the same period in 2020 resulting from the increase in revenue recognized under the Regeneron Agreement. The increase was primarily due to our increased activities under the Regeneron Agreement related to ADI-002.

Research and development

	Three Months Ended September 30,	
	2021	2020
Payroll and personnel expenses ⁽¹⁾	\$ 4,559	\$ 4,698
Costs incurred under agreements with consultants, CMOs, and CROs	3,904	2,119
Lab materials, supplies, and maintenance of equipment used for research and development activities	1,203	1,312
Other research and development expenses ⁽²⁾	2,260	813
Total research and development expenses	\$ 11,926	\$ 8,942

⁽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 \$3.0 million, or 33%, during the three months ended September 30, 2021 compared to the same period in 2020. The increase in research and development expenses was primarily due to a \$1.4 million increase in facility and other expenses, a \$1.3 million increase in CRO, consulting and other externally sponsored research expenses, and a \$0.4 million increase in CMO expenses. These increases were partially offset by decreases in lab materials and supplies of \$0.1 million and in personnel expenses of \$0.1 million, which include salaries, benefits, and bonuses. Due to the competitive job market, we have experienced a slower than expected net growth in headcount of employees involved in research and development activities, which resulted a decrease in stock-based compensation expense of \$0.2 million.

General and administrative

General and administrative expenses decreased by \$2.5 million, or 33%, during the three months ended September 30, 2021 as compared to the same period in 2020. The decrease in general and administrative expenses was primarily due to a decrease in professional fees of \$1.7 million, which includes a \$1.5 million decrease in legal fees and a \$0.4 million decrease in audit fees, related to the Merger in 2020, offset by a \$0.2 million increase in other professional fees including investor

relations, IT management, and other enterprise solutions. In addition, there was a decrease of \$0.8 million in payroll and personnel expenses, consisting of a decrease of stock-based compensation expense of \$0.3 million and consultant fees of \$0.7 million, offset by an increase in salary, bonus, and benefits of \$0.2 million.

Interest income

Interest income decreased by \$0.1 million, or 97%, during the three months ended September 30, 2021 as compared to the same period in 2020, which was primarily to a decrease in marketable debt securities in 2021 and decrease in interest rates, which lowered return on investments.

Interest Expense

Interest expense was the same during the three months ended September 30, 2021 as compared to the same period in 2020 due to the straight-line non-cash amortization of costs incurred in connection with the Loan Agreement entered into in April 2020.

Other income (expense), net

Other income (expense), net decreased by \$1.0 million, during the three months ended September 30, 2021 as compared to the same period in 2020. The decrease was primarily due to realized gain recognized in 2020 related to a change in fair value of the redeemable convertible preferred stock warrant liability prior to their conversion to warrants to purchase common stock upon closing of the Merger in September 2020. For the quarter ended September 30, 2021, we recorded \$0.2 million in loss from disposals of fixed assets in the Boston office as a result of the sublease of the office space in August 2021. We also recorded \$55,000 in franchise taxes and incurred realized losses related to foreign exchange of approximately \$6,000.

Income tax expense

We recognized an income tax benefit of \$11,000 during the three months ended September 30, 2021 in comparison to \$0 during the three months ended September 30, 2020. The change was due to the tax effect of the reduction in the deferred tax liability associated with the basis differences from IPR&D.

Comparison of the Nine Months Ended September 30, 2021 and 2020

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

	Nine Months Ended September 30,		Change	% Change
	2021	2020		
Revenue – related party	\$ 4,262	\$ 12,493	\$ (8,231)	-66 %
Operating expenses:				
Research and development	34,285	24,651	9,634	39 %
General and administrative	15,868	17,684	(1,816)	-10 %
Total operating expenses	50,153	42,335	7,818	18 %
Loss from operations	(45,891)	(29,842)	16,049	54 %
Interest income	54	704	(650)	-92 %
Interest expense	(151)	(84)	67	80 %
Other income (expense), net	(312)	(1,174)	862	-73 %
Loss before income tax provision (benefit)	(46,300)	(30,396)	(15,904)	52 %
Income tax provision (benefit)	(114)	(2,676)	2,562	-96 %
Net loss	\$ (46,186)	\$ (27,720)	\$ (18,466)	67 %

Revenue

Revenue decreased by \$8.2 million, or 66%, for the nine months ended September 30, 2021 compared to the same period in 2020 resulting from the decrease in revenue recognized under the Regeneron Agreement. This decrease in revenue was primarily due to our achievement of a milestone under the Regeneron Agreement in June 2020 relating to the selection of a clinical candidate for ADI-002. This resulted in an increase in the transaction price of \$10.0 million and recognition of an

additional cumulative catch-up of revenue of \$5.0 million in June 2020. In addition, in the first quarter of 2021, we recorded a \$4.0 million revenue reduction 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.

Research and development

	Nine Months Ended September 30,	
	2021	2020
Payroll and personnel expenses ⁽¹⁾	\$ 15,315	\$ 11,295
Costs incurred under agreements with consultants, CMOs, and CROs	9,563	7,595
Lab materials, supplies, and maintenance of equipment used for research and development activities	3,415	3,374
Other research and development expenses ⁽²⁾	5,992	2,387
Total research and development expenses	\$ 34,285	\$ 24,651

⁽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 \$9.6 million, or 39%, during the nine months ended September 30, 2021 compared to the same period in 2020. The increase in research and development expenses was primarily due to an increase of \$4.0 million in payroll and personnel expenses, which includes salaries, benefits, and bonuses due to increases in headcount of employees involved in research and development activities, as well as an increase in stock-based compensation expense of \$2.1 million due to higher option grant activity. In addition, there was an increase of \$3.3 million in fees incurred for CRO, consultants, and other externally sponsored research and \$3.6 million increase in facility and other expenses. This increase was primarily due to ramping up of clinical development activities related to ADI-001, our first product candidate. These increases were offset by decreases in CMO expenses of \$1.3 million related to ramping up of manufacturing activities in early 2020.

General and administrative

General and administrative expenses decreased by \$1.8 million, or 10%, during the nine months ended September 30, 2021 as compared to the same period in 2020. The decrease in general and administrative expenses was primarily due to a decrease of \$5.9 million in professional fees which includes decreases of \$4.6 million in legal fees and \$1.7 million in audit fees, due to higher expenses related to the Merger in 2020. These decreases in professional fees were offset by an increase of \$0.4 million in other professional fees consisting of investor relations, IT management, and other enterprise solutions. In addition, the decreases in general and administrative expenses were offset by a \$1.2 million increase in payroll and personnel expenses, which includes salaries, benefits, bonuses, and temporary contractor fees due to higher stock-based compensation expenses of \$2.5 million caused by increased option grant activity and higher salaries and benefits of \$0.6 million reduced by lower temporary contractor fees of \$1.9 million. Further, there was an increase of \$2.9 million in facilities and other expenses, of which \$1.7 million relates to rent, depreciation and equipment maintenance, and \$1.2 million relates to our director and officer liability insurance.

Interest income

Interest income decreased by \$0.7 million, or 92%, during the nine months ended September 30, 2021 as compared to the same period in 2020, which was primarily attributable to a decrease in marketable debt securities in 2021 and decrease in interest rates, which lowered return on investments.

Interest Expense

Interest expense increased by \$67,000, during the nine months ended September 30, 2021 as compared to the same period in 2020 due to the non-cash amortization of costs incurred in connection with the Loan Agreement entered into in April 2020.

Other income (expense), net

Other income (expense), net decreased by \$0.9 million, or 74%, during the nine months ended September 30, 2021 as compared to the same period in 2020. The decrease was primarily due to realized gain recognized in 2020 related to a change in fair value of the redeemable convertible preferred stock warrant liability prior to their conversion to warrants to purchase common stock upon closing of the Merger in September 2020. During the nine months ended September 30, 2021, we recorded \$0.2 million related to disposal of fixed assets related to the sublease of the Boston lease in August 2021, \$99,000 of franchise taxes, and approximately \$28,000 of realized loss due to foreign exchange.

Income tax expense

We recognized an income tax benefit of \$0.1 million during the nine months ended September 30, 2021 in comparison to \$2.7 million during the nine months ended September 30, 2020. The reduction in benefit relates to the nature of discrete tax benefit during the nine months ended September 30, 2021, as a result of the recognition of a net operating loss carryback under the CARES Act. Income tax benefit of \$0.1 million for the nine months ended September 30, 2021 was due to the tax effect of the reduction in the deferred tax liability associated with the basis differences from IPR&D.

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. As of September 30, 2021, we have \$192.2 million in cash and cash equivalents.

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 these annual consolidated financial statements.

Loan Agreement

On April 28, 2020, we entered into the Loan Agreement with Pacific Western Bank for a term loan not exceeding \$12.0 million to finance leasehold improvements for our facilities in Redwood City, CA, with an interest rate equal to the greater of 0.25% above the Prime Rate (as defined in the Loan Agreement) or 5.00%. In connection with the entrance into the Loan Agreement, we issued Pacific Western Bank a warrant to purchase shares of our Series B redeemable convertible preferred stock at an exercise price of \$1.4034 per share. Such warrant was initially exercisable for 42,753 shares of our Series B redeemable convertible preferred stock. Upon the closing of the Merger, it was exchanged for a warrant to purchase 5,301 shares of common stock at an exercise price of \$11.32 per share and shall be exercisable for an additional number of shares of common stock equal to 1.00% of the aggregate original principal amount of all term loans made pursuant to the Loan Agreement (up to an aggregate maximum of 15,903 shares of common stock). The New PacWest Warrant was exercised in February 2021 and the net issuance was 1,806 shares of common stock. Further, 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. As of September 30, 2021, we were in compliance with such covenants and had no indebtedness outstanding under the Loan Agreement. To date, we have not drawn any funds from the Loan Agreement.

On October 21, 2021, we entered into the Loan Amendment under which Pacific Western Bank will provide one or more Term Loans, as well as Non-Formula Ancillary Services which shall not exceed \$5.5 million in the aggregate. The aggregate sum of the outstanding Term Loans and Non-Formula Ancillary Services shall at no time exceed \$15.0 million, with each term loan to be in an amount of not less than \$1.0 million. Pursuant to the Loan Amendment, the interest rate for

the Terms 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%.

Public Offering and Concurrent Private Placement

In February 2021, the Company completed an underwritten public offering of 10,575,513 shares of the Company's 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 \$128.7 million.

In connection with the offering, the Company also entered into a stock purchase agreement with certain existing investors for 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. The Company 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. The shares sold in the private placement were not registered under the Securities Act.

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. As of September 30, 2021, no shares were sold under the 2021 Sales Agreement.

Future Funding Requirements

We have incurred losses since inception and have incurred losses of \$14.0 million and \$46.2 million for the three and nine months ended September 30, 2021, respectively, and \$14.8 million and \$27.7 million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2021, we had an accumulated deficit of \$152.5 million.

As of September 30, 2021, we had cash and cash equivalents of \$192.2 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 financial statements as of September 30, 2021 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 U.S. and global economic conditions that may impact our ability to access capital on terms anticipated, or at all; and
- the post-Merger costs associated with being a public company.

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

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

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

Summary Statement of Cash Flows

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

	Nine Months Ended September 30,	
	2021	2020
Net cash provided by (used in):		
Operating activities	\$ (37,608)	\$ (28,207)
Investing activities	282	102,769
Financing activities	145,222	36
Net increase in cash, cash equivalents and restricted cash	<u>\$ 107,896</u>	<u>\$ 74,598</u>

Cash Flows from Operating Activities

Net cash used in operating activities was \$37.6 million for the nine months ended September 30, 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 \$46.2 million, adjusted for non-cash activities of \$12.1 million. The non-cash activities are composed of depreciation expense of \$1.2 million, loss from disposal of fixed assets of \$0.2 million, a non-cash lease expense of \$2.2 million related to amortization of right of use (ROU) asset, stock-based compensation expense of \$8.2 million, an amortization of deferred debt issuance costs of \$0.1 million, a non-cash expense for impairment of in-process research and

development (IPR&D) of \$1.2 million, and a gain on the remeasurement of contingent consideration liability of \$1.0 million. Changes in operating assets and liabilities were composed of decreases of \$0.5 million in prepaid expenses and other current assets, \$3.9 million in contract liabilities related to the Regeneron Agreement, \$1.1 million in operating lease liabilities, and \$1.2 million in accrued and other current liabilities. These decreases were partially offset by increases of \$3.1 million in accounts payable and \$0.1 million in other non-current liabilities related to security deposit held for the sublease of the Boston lease. The changes in prepaid expenses and other current assets, accounts payable, and accrued and other liabilities resulted from the timing of payments to our service providers.

Net cash used in operating activities was \$28.2 million for the nine months ended September 30, 2020. 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 \$27.7 million, adjusted for an increase in prepaid expenses and other current assets of \$5.0 million a decrease in contract liabilities of \$2.5 million, and an increase in other non-current assets of \$1.6 million partially offset by non-cash charges for depreciation expense of \$0.9 million, and stock-based compensation expense of \$3.6 million, an increase in accounts payable of \$1.4 million and an increase in accrued and other current liabilities of \$1.7 million. The increase in prepaid expenses and other current assets resulted from the prepayment for director and officer liability insurance after the close of the Merger, timing of payments to our CROs and CMOs and an increase in federal tax receivable. Increases in accounts payable and accrued and other liabilities resulted from the timing of payments to our service providers.

Cash Flows Used in Investing Activities

Net cash provided by investing activities was \$0.3 million for the nine months ended September 30, 2021, which consisted of proceeds from sales and maturities of marketable debt securities of \$10.3 million, partially offset by purchases of property and equipment of \$10.0 million related to the construction of our new building in Redwood City, CA.

Net cash provided by investing activities was \$102.8 million for the nine months ended September 30, 2020, which consisted of cash and restricted cash acquired in connection with the Merger of \$64.1 million, proceeds from maturities of marketable debt securities of \$45.0 million, partially offset by purchases of marketable debt securities of \$5.7 million and purchases of property and equipment of \$0.6 million.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$145.2 million for the nine months ended September 30, 2021, was related to net cash proceeds received from our public offering in February 2021 of \$143.8 million, cash proceeds of \$1.6 million from exercise of stock options and deferred debt issuance costs of \$0.2 million.

Net cash provided by financing activities was less than \$0.1 million for the nine months ended September 30, 2020, due to cash proceeds of \$0.2 million from exercise of stock options partly offset by payment of debt issuance costs of \$0.2 million.

Contractual Obligations and Other Commitments

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 subleased 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, MA. The initial lease term commenced on July 30, 2021 and expires on November 30, 2021. In October 2021, we extended the lease term to March 31, 2022. The base rent is approximately \$9,000 per month.

Critical Accounting Policies, Significant Judgments and Use of 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 (as discussed in our 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. 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, 2020 filed with the SEC on March 11, 2021.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements.

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 financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2021, we had cash and cash equivalents of \$192.2 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.

We do not believe that inflation, interest rate changes or foreign currency exchange rate fluctuations have had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures.

Definition and limitations of disclosure controls

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. Our management evaluates these controls and procedures on an ongoing basis.

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.

Evaluation of disclosure controls and procedures

During the preparation of our consolidated financial statements as of and for the year ended December 31, 2020 and the quarter ended September 30, 2021, we identified material weaknesses in our internal control over financial reporting. A company’s internal control over financial reporting is a process designed by, or under the supervision of, a company’s principal executive and principal financial officers, or persons performing similar functions, and effected by a company’s Board of Directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. Under standards established by the Public Company Accounting Oversight Board (PCAOB), a material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

In connection with the audit of our financial statements as of and for the quarters ended September 30, 2021, and 2020, we identified material weaknesses in our internal control over financial reporting. The material weaknesses we identified were as follows:

- we did not design or maintain an effective control environment commensurate with our financial reporting requirements due to lack of a sufficient number of accounting professionals with the appropriate level of experience and training;
- we did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, and monitoring controls maintained at the corporate level were not at a sufficient level of precision to provide for the appropriate level of oversight of activities related to our internal control over financial reporting;
- we did not design and maintain effective controls over segregation of duties with respect to the preparation and review of account reconciliations as well as creating and posting manual journal entries; and
- we did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose complex transactions.

Our management, including our CEO and our CFO, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2021. This evaluation is performed to determine if our disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure and are effective to provide reasonable assurance that such information is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and forms. Due to the material weaknesses described above and the Company's evaluation, the CEO and CFO have concluded that our disclosure controls and procedures were not effective as of March 31, 2021.

Remediation of Material Weaknesses in Internal Control over Financial Reporting

The material weaknesses that we identified resulted from an insufficient complement of resources with an appropriate level of accounting knowledge, experience, and training to address accounting for complex, non-routine transactions. We are currently in the process of remediating the material weakness and have taken and continue to take steps that we believe will address the underlying causes of the material weakness, primarily by hiring additional accounting and finance personnel with technical accounting and financial reporting experience, enhancing our training programs within our accounting and finance department, and enhancing our internal review procedures during the financial statement close process. During the preparation of this Quarterly Report on Form 10-Q, our management has implemented certain additional substantive and analytical review procedures to ensure that information required to be disclosed by us in this report is recorded, processed, summarized, and reported within the time periods specified in the Commission's rules and forms.

Our management, under the supervision of our CEO and CFO has undertaken a plan to remediate the material weaknesses identified above. The remediation efforts and progress summarized below are intended to address and remediate the identified material weaknesses:

- In the first quarter of 2021, we engaged a permanent Vice President, Corporate Controller, and a Senior Manager of Finance, together with third-party consultants, to improve and oversee all aspects of accounting operations, financial reporting, and Sarbanes-Oxley (SOX) compliance;
- We also successfully implemented a new Enterprise Resource Planning (ERP) system, Microsoft 365 Business Central, in January 2021, replacing Quickbooks and providing efficiency and financial controls. We provided appropriate training to all key accounting personnel who are responsible for posting and reviewing journal entries; and
- In the first quarter of 2021, we reevaluated our existing internal controls and, in the second quarter, we implemented additional controls to enhance our internal control environment. Since the third quarter of 2021, we have been performing internal control testing to ensure these controls are operating effectively as designed and implemented.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. As a result of the COVID-19 pandemic, since March 2020, we have requested that our employees work remotely, as appropriate. We have not identified any material changes in our internal control over financial reporting as a result of these changes to the working environment. We are continually monitoring and assessing the COVID-19 situation to determine any potential impacts on the design and operating effectiveness of our internal controls over financial reporting.

PART II—OTHER INFORMATION

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 September 30, 2021, 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 September 30, 2021, our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, 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.

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.

We have 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. Our product candidates including ADI-001 and ADI-002, have not yet been evaluated in clinical trials. 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. For the quarters ended September 30, 2021 and 2020, we reported net losses of \$14.0 million and \$14.8 million, respectively. As of September 30, 2021, we had an accumulated deficit of \$152.5 million.

We expect to incur significant expenditures for the foreseeable future, and we expect these expenditures to increase as we continue our research and development of, and seek regulatory approvals for, product candidates based on our gamma delta T cell platform, including ADI-001 and ADI-002. 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 raise substantial doubts about our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations.

We have incurred operating losses to date and it is possible we will never generate a profit. Our financial statements included elsewhere in this Quarterly Report on Form 10-Q have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of these uncertainties related to our ability to operate on a going concern basis. If we are unable to raise sufficient capital when needed, our business, financial condition and results of operations will be harmed, and we will need to significantly modify our operational plans to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The potential inclusion of a going concern explanatory paragraph by our auditors, our lack of cash resources and our potential inability to continue as a going concern may negatively impact our share price and our ability to raise new capital or to enter into critical contractual relations with third parties due to concerns about our ability to meet our contractual obligations.

Risks Related to Our Product Candidates

Our business is highly dependent on the success of ADI-001 and ADI-002. If we are unable to obtain approval for ADI-001 or ADI-002 and effectively commercialize ADI-001 or ADI-002 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 candidates, ADI-001 and ADI-002. ADI-001 is in the early stages of development and we initiated first-in-human clinical trial to assess safety and efficacy of ADI-001 in NHL patients in March 2021. ADI-002 is also in the early stage of development and we intend to file an IND in the second quarter of 2022.

Our preclinical results to date may not predict results for our planned trials or any future studies of ADI-001 and ADI-002 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 and ADI-002, 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 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 therapy 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 developed by us, 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 INDs 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. Additionally, we plan to submit an IND for our product candidate ADI-002 in the second quarter of 2022 and, subject to the FDA's regulatory process for review of INDs, initiate Phase 1 clinical trials of ADI-002 in the second half of 2022. However, our timing of filing on ADI-002 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 IND 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. The inability to initiate a clinical trial on ADI-001 or ADI-002 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 institutional review board (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 IND 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 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 and other indications in geographies which are affected by 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 U.S. 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 U.S.;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- 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 ADI-002 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 and ADI-002. 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 U.S. or overseas. If we are unable to successfully market and distribute our products, our business, results of operations and prospects could be materially adversely affected.

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

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

Specifically, engineered T cells face significant competition in both the CAR and 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 of Product Candidates

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 and ADI-002. 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 product to satisfy demands to support clinical trials for any of our product candidates. Very few companies have experience in manufacturing gamma delta T cell therapy derived from blood of healthy 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 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 Exclusive License and Collaboration Agreement with 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.

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 planned clinical trials for ADI-001 and ADI-002. 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.

We believe that our cash and cash equivalents will be sufficient for us to continue as a going concern for at least one year from the issuance date of the accompanying consolidated financial statements. 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, we may not be able to incur indebtedness if the ongoing macroeconomic effects of the COVID-19 pandemic, including certain actions taken by U.S. or other governmental authorities, such as decreases in short-term interest rates as announced by the Federal Reserve, cause the closure of banks for an extended period of time or a sudden increase in requests for indebtedness at one time by many potential borrowers, either or both of which could overwhelm the banking industry.

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.

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 or other business interruption. 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 COVID-19, 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 U.S. and international markets, including as a result of prolonged economic downturn or recession. On March 11, 2020, the World Health Organization declared the recent outbreak of COVID-19 a pandemic. As a result, national, state, and local authorities

have recommended social distancing and imposed or are considering quarantine, shelter-in-place, curfew, and similar isolation measures, including government orders and other restrictions on the conduct of business operations, which has resulted in significant unemployment levels, decreased productivity, decreases in certain non-COVID-19 healthcare activities and healthcare utilization. Such measures have had, and are likely to continue to have, adverse impacts on the U.S. 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 may affect the operations of the FDA and other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates. The evolving 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 ADI-002 or our other product candidates. Additionally, while the potential economic impact brought by, and the duration of the COVID-19 pandemic is 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 ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. Due to the uncertain and rapidly evolving nature of current conditions in the U.S. and around the world, we cannot reasonably estimate the length or severity of the COVID-19 pandemic or the related response, including the length of time it may take for normal economic and operating conditions to resume. 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.

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, foreign and domestic inspections by FDA have largely been on hold with FDA announcing plans in July 2020 to resume prioritized domestic inspections. Should FDA determine that an inspection is necessary for approval of a marketing application and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. 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 Government 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. The U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully, offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchasing, leasing, ordering or arranging for the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers, among others, on the other. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act and the civil monetary penalties statute;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal government programs that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government, including federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act (HIPAA), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health (HITECH) and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services’ Center for Medicare and Medicare Services (CMS) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we may be subject to analogous state and foreign healthcare laws described above, among others, some of which may be broader in scope. For example, we may be subject to the following: state Anti-Kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, or that apply regardless of payor; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws requiring the registration of pharmaceutical sales and medical representatives; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Furthermore, we are subject to General Data Protection Regulation (GDPR) and other ex-US protections, as discussed further below.

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 U.S. 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. 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 U.S. 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.

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 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, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. 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 and expected 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. 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.

Legal, regulatory, political and economic uncertainty surrounding the exit of the United Kingdom (U.K.) from the European Union may be a source of instability in international markets, create significant currency fluctuations, adversely affect operations in the U.K. and pose additional risks to our business.

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the U.K. and the EU, the U.K. was subject to a transition period until December 31, 2020 (Transition Period), during which EU rules continued to apply. Negotiations between the U.K. and the EU are expected to continue in relation to the customs and trading relationship between the U.K. and the EU following the expiry of the Transition Period. Such a withdrawal from the EU is unprecedented, and it is unclear how the U.K.'s access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our business.

The uncertainty concerning the U.K.'s legal, regulatory, political, and economic relationship with the EU after the Transition Period may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise). It could also lead to a period of considerable uncertainty in relation to the regulatory process for drug development and approval in Europe, and make it more costly or difficult to advance our product candidates in the EU and U.K.

Our ability to use net operating losses and research and development credit to offset future taxable income may be subject to certain limitations as a result of the Merger.

To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period), such corporation’s ability to use its pre-change net operating loss carryforwards (NOLs) and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations, if we experienced an ownership change. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even as we attained profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

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.

We have identified material weaknesses in our internal control over financial reporting. Failure to achieve and maintain effective internal control over financial reporting could harm our business and negatively impact the value of our common stock.

We have identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the audit of our financial statements as of and for the quarters ended September 30, 2021 and 2020, we identified material weaknesses in our internal control over financial reporting. The material weaknesses we identified were as follows: (i) we did not design or maintain an effective control environment commensurate with our financial reporting requirements due to lack of a sufficient number of accounting professionals with the appropriate level of experience and training; (ii) we did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, and monitoring controls maintained at the corporate level were not at a sufficient level of precision to provide for the appropriate level of oversight of activities related

to our internal control over financial reporting; (iii) we did not design and maintain effective controls over segregation of duties with respect to the preparation and review of account reconciliations as well as creating and posting manual journal entries; and (iv) we did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose complex transactions.

Additionally, each of the control deficiencies could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies constitute material weaknesses.

Risks Related to Reliance on Third Parties

Risks Related to Third Parties

If our collaboration with Regeneron is terminated, or if Regeneron materially breaches our 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 our agreement with Regeneron, Regeneron provided us with an upfront payment of \$25 million and additional payments for research funding 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. 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. 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 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 ICP's and our business could be adversely affected.

The exclusivity obligations under the Regeneron agreement have 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 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 for ADI-001 and ADI-002, and we may have to rely on third parties to produce and process our other 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, three vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020 and early 2021, and more are likely to be authorized in the coming months. 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 U.S. 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 U.S. We are not permitted to market any biological drug product in the U.S. 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 Current 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 current 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 U.S. 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 U.S. 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 ADI-001 and ADI-002 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.

Given the molecular similarities between ADI-001 and ADI-002, we may have additional difficulties progressing any clinical trial of ADI-002, if emerging data from future clinical trials of ADI-001 have safety or other issues.

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 U.S. 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 U.S., or a patient population greater than 200,000 in the U.S. when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the U.S. will be recovered from sales in the U.S. 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 U.S. 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 candidate and may change as more patient data becomes available and are 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 candidate 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. 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 future clinical trials of our product candidate 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.

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 U.S., including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the U.S. have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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 cGCPs 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 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 manufacturer's 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 U.S. or abroad. For example, certain policies of the former U.S. President's administration may impact our business and industry. Namely, the former U.S. President's administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. 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.

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 payers and reduce the willingness of physicians to use our product candidates.

In the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. 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 U.S. Congressional inquiries and federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs 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 U.S. and in selected foreign jurisdictions. Increased efforts by governmental and third-party payors in the U.S. 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 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 U.S. 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. In particular, in 2010 the Affordable Care Act (ACA) was enacted. The Affordable Care Act and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our product candidates, under the Medicaid drug rebate program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid drug rebate program, extended the Medicaid drug rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. Additionally, the Affordable Care Act allowed states to implement expanded eligibility criteria for Medicaid programs, imposed a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program and implemented a new

Patient-Centered Outcomes Research Institute. We are still unsure of the full impact that the Affordable Care Act will have on our business.

There remain legal and political challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted. The Further Consolidated Appropriations Act (H.R. 1865) permanently eliminated, effective January 1, 2020, the Affordable Care Act's mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018 (the BBA) among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In December 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the Affordable Care Act risk adjustment program payment parameters have been updated annually.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2030, unless additional Congressional action is taken. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, as well as subsequent legislation, these reductions have been suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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.

In addition, there has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for drugs. At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs Health and Human Services (HHS) to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and

address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on August 6, 2021 CMS announced a proposed rule to rescind the Most Favored Nations rule. Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors have been delayed until January 1, 2023. Further, implementation of these changes and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates if we obtain regulatory approval;
- our ability to set a price that 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.

Risk Related to Our Intellectual Property

Risk 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 requires 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 U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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, or 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. U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S.

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 U.S., 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 U.S. 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 U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include IPR, ex parte re-examination and post grant review in the U.S., 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 Intellectual Property Laws

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

As is the case with other 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 U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

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

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>Sublease Agreement, dated July 19, 2021, by and between Adicet Bio, Inc. and RFS Opco LLC (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 July 23, 2021).</u>
10.2	<u>Fourth Amendment to Loan and Security Agreement, dated October 21, 2021, by and between Adicet Therapeutics, Inc. and Pacific Western Bank (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 October 25, 2021).</u>
10.3	<u>Affirmation and Amendment of Guaranty, dated October 21, 2021, by and between Adicet Bio, Inc. and Pacific Western Bank (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 October 25, 2021).</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: November 10, 2021

By:

/s/ Chen Schor

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

Date: November 10, 2021

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: November 10, 2021

**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, Nick Harvey, certify that:

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

/s/ Nick Harvey

Nick Harvey

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: November 10, 2021

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

In connection with the Quarterly Report on Form 10-Q of Adicet Bio, Inc. (the "Company") for the quarter ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, that, to the best of their knowledge:

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

/s/ Chen Schor

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

Date: November 10, 2021

/s/ Nick Harvey

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

Date: November 10, 2021
