

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

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)

81-3305277
(I.R.S. Employer
Identification No.)

500 Boylston Street, 13th Floor
Boston, MA 02116
(857) 315-5528

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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 June 30, 2020, the aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates was approximately \$40.0 million based on a closing price of \$15.05 per share as quoted by The Nasdaq Global Market as of such date. In determining the market value of non-affiliate common stock, shares of the registrant's common stock beneficially owned by officers, directors and affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 10, 2021, there were 31,780,347 shares of common stock, \$0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates by reference certain information from the registrant's definitive Proxy Statement for its 2021 annual meeting of shareholders, scheduled to be held on April 27, 2021 which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year end of December 31, 2020. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

Summary of the Material and Other 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 approved 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.
- 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 our 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.
- We do not currently operate our own manufacturing facility, which would require significant resources and any failure to successfully manufacture our products could adversely affect our clinical trials and the commercial viability of our product candidates.

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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 Annual Report on Form 10-K 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 AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, 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 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 Annual Report on Form 10-K, 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K, and we believe these industry publications and third-party research, surveys and studies are reliable.

PART I

All brand names or trademarks appearing in this report are the property of their respective owners. Unless the context requires otherwise, references in this report to “Adicet Bio,” “Adicet,” “the “Company,” “we,” “us” and “our” refer to Adicet Bio, Inc. and its subsidiaries, as applicable.

Item 1. Business.

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 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. Gamma delta cells are unique because 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 may 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 extracting gamma delta T cells from the blood of healthy donors, and results in the potential to treat up to 1,000 patients per batch 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 gamma delta T cells and associated modifications, we are initially developing product candidates in oncology, both for hematological malignancies and for solid tumors. In October 2020, the United States (U.S.), Food and Drug Administration (FDA), cleared our Investigational New Drug (IND) application for ADI-001, our lead product candidate, for the treatment of Non-Hodgkin’s Lymphoma (NHL). The active IND enables us to initiate the first-in-human clinical trial to assess safety and efficacy of ADI-001 in NHL patients in the first quarter of 2021. The Phase 1 study for ADI-001 will enroll up to 80 late-stage NHL patients at a number of cancer centers across the U.S. The study includes a dose finding portion followed by dose expansion cohorts to explore the activity of ADI-001 in multiple subtypes of NHL. Site initiation activities are underway and interim clinical data from this study are expected in 2021. We intend to file an IND with the FDA in late 2021 for ADI-002, our first solid tumor product candidate.

Gamma delta T cells have unique attributes that we believe make them especially well-suited to be used for cancer therapy. Approximately 95% of T cells in circulation are so-called alpha beta T cells, named after the proteins that make up the cells’ T cell receptor (TCR). The remaining T cells include a population that makes up between 1% and 5% of all T cells, the gamma delta T cells, along with a few other cell types. Distinct among immune cell populations, we believe gamma delta T cells may have the following combination of attributes:

- Can be used in patient irrespective of the tissue-types of the patient i.e., a “universal” product;
- Can be used “off-the-shelf” after being expanded from healthy donors;
- Are actively cytotoxic to tumor cells;
- May functionally persist in patients for clinically meaningful periods or time;
- Can replicate in an appropriate and measured way after manufacture and administration; Can have their reactivity to tumor cells enhanced further by the addition of a CAR;
- Express both T cell and natural killer, or NK, cell receptors, facilitating both adaptive and innate anti-tumor immune responses; and
- Can be manufactured potentially in large numbers to facilitate the consistent treatment of many patients and avoids the cumbersome nature and expense of isolating cells from each patient.

By contrast, approved CAR-T cell therapies, as well as the majority of CAR-T cell therapies in clinical development, are based on a different population of T cells, known as alpha beta T cells, which have the ability to attack healthy tissues if they are not immunologically matched to the patient. For this reason, the majority of alpha-beta-T-cell-derived CAR-T cell products are custom-generated from cells isolated from each patient. Gamma delta T cells, by contrast, do not in principle require

immunological matching and therefore cells isolated from healthy donors can potentially be administered to any patient. This may enable cell therapy products based on gamma delta T cells to be manufactured in bulk and be distributed as readily available off-the-shelf products. In animal models and early third-party clinical trials, gamma delta T cells do not expand in healthy tissues, indicating that they may be associated with a lower risk of life-threatening immune responses. In addition to their ability to circulate, gamma delta T cells have an inherent capacity to locate in tissues and recognize and attack cancerous cells.

In comparison to a number of NK cell therapies currently in development, CAR-modified gamma delta T cells functionally persist in non-clinical models for protracted periods of time and are designed to persist after single or repeat dosing of patients for clinically meaningful periods. Our manufacturing process results in highly homogeneous cell populations that we have observed to display potent anti-tumor activity in non-clinical models. Unlike most NK cells, that only exhibit characteristics on innate lymphocytes, gamma delta T cells display features of both innate and adaptive anti-tumor immunity and readily recognize and kill tumor cells with and without expression of CARs. Additionally, we believe that our short proprietary process to manufacturing CAR-modified gamma delta T cells is not as complex, without any “feeder” cell lines, and compares favorably to alternatives used in the manufacture of expanded allogeneic NK cell-based therapies.

ADI-001 is a gamma delta T-cell product candidate into which we introduced a CAR that specifically recognizes CD20, a highly expressed surface protein found on the majority of NHLs. We are developing a highly efficient and robust process to activate, engineer and manufacture product candidates derived from peripheral blood cells of healthy donors. We are developing processes to produce these cells in bulk under conditions that meet current Good Manufacturing Practices, that is, are cGMP-compliant, to generate an inventory of cell product that is readily available to patients on demand “off-the-shelf” at clinical sites. Gamma delta T cells engineered with anti-CD20 CAR have demonstrated potent antitumor activity in preclinical models, leading to long-term control of tumor growth. In October 2020, FDA cleared our IND application for ADI-001 for the treatment of NHL. The active IND enables us to initiate the first-in-human clinical trial to assess safety and efficacy of ADI-001 in NHL patients in the first quarter of 2021. We believe that ADI-001 has the potential to benefit patients that have NHL while also providing clinical validation of our gamma delta T-cell platform technology.

In addition to potentially providing access to immunocellular therapies to a broader set of patients with hematological malignancies, we believe that our gamma-delta platform technology is well-positioned to bring these therapies to patients with solid tumors. ADI-002 is a product candidate containing a CAR directed against Glypican-3, or GPC3, a tumor antigen that is highly expressed in hepatocellular carcinoma, or HCC, and other tumors such as gastric cancer and squamous cell carcinoma of the lung. ADI-002 has demonstrated dose-dependent antitumor activity in animal models and we intend to file an IND application with the FDA in late 2021 for ADI-002. Subject to the FDA regulatory process for review of INDs, we intend to initiate a clinical trial and treat the first patient with ADI-002 in 2022.

Our solid tumor efforts are further complemented by our proprietary T cell receptor-like antibody (TCRL), platform technology, a monoclonal antibody technology which enables the generation of CARs that recognize tumor antigens inside tumor cells, also known as intracellular proteins. These intracellular proteins are processed by the cell and presented by antigen-presenting molecules encoded by the major histocompatibility complex, (MHC). We believe that the ability to selectively bind to tumor antigens derived specifically from intracellular proteins is a critical advantage to immunocellular therapy due to the scarcity of tumor-specific surface antigens on solid tumors. Our approach to generating CARs for some product candidates takes advantage of this ability.

Our management team has extensive experience in the discovery and development of immunocellular therapies with prior experience at leading biopharmaceutical organizations including Novartis, Fate, Celgene, Amgen and Onyx. Our founder and former President and Chief Executive Officer (CEO), Aya Jakobovits, was the President and founding CEO of Kite Pharma Inc., (Kite). Prior to the business combination between Adicet Therapeutics, Inc, and resTORbio, Inc on September 2020, we had received investments valued at an aggregate of approximately \$124 million from investors that include entities affiliated with OrbiMed Advisors LLC, aMoon Fund, Johnson & Johnson Innovation-JJDC, Inc, Novartis Venture Fund, and Regeneron Pharmaceuticals, Inc (Regeneron).

Pipeline

We have a pipeline of wholly owned product candidates. As part of a five-year collaboration with Regeneron pursuant to an agreement signed in 2016, Regeneron has the option to obtain development and commercial rights for a certain number of product candidates, and we have an option to participate in the development and commercialization of these potential products or are entitled to royalty payments by Regeneron. Immunocellular therapy product candidates developed and commercialized by us under our agreement with Regeneron will be subject to payment of royalties to Regeneron. To date, Regeneron has not exercised an option on any of our candidates. For additional information on our agreement with Regeneron, please see “Adicet Business—Strategic Agreements” beginning on page 27 of this Annual Report on Form 10-K. Our pipeline of additional product candidates includes ADI-00x, for which we expect to file an IND for solid tumor indications in 2022 and an IND for solid tumor and hematological indications in 2023.



Strategies

Our objective is to be the leading biotechnology company developing CAR-modified gamma delta T cells for oncology and for additional indications. We plan to achieve this objective through the efficient clinical development, regulatory approval and commercialization of our lead ADI-001 product candidate. We intend to achieve two key objectives with the development program for ADI-001:

- bring a meaningful product to patients by developing ADI-001 in NHL; and
- validate the gamma delta T cell platform to enable rapid application to additional oncology indications.

To achieve these objectives, we intend to evaluate in our clinical trials on the efficacy and safety profile of our candidate in comparison to the currently approved autologous (manufactured from the patient’s own cells) alpha-beta based T-cell therapy in similar patient populations of NHL, and if approved make the product available off the shelf.

- **Advance ADI-002 into clinical development.** ADI-002, our lead solid tumor product candidate, is currently undergoing preclinical studies. We intend to file an IND application with the FDA in late 2021 for ADI-002. Subject to the FDA regulatory process for review of INDs, we intend to initiate a clinical trial and treat the first patient with ADI-002 in 2022. Our goal is to develop ADI-002, both in monotherapy and in combination with standard of care agents, in a number of solid tumors that express high levels of glypican 3 protein, or GPC3, the cell surface molecule targeted by the product.
- **Potential for outpatient administration.** While we expect that the initial subjects treated with gamma delta T cell-based therapies in clinical studies will be hospitalized for a minimum of 24-hour observation after infusion, a favorable tolerability profile may allow administration of such therapies in an outpatient setting. This would represent a significant competitive advantage for gamma delta T cell-based therapies as compared to existing approved CAR-T cell therapies.

- **Continue to innovate and invest in the gamma delta T cell platform and pipeline.** We expect to continue to develop product candidates in oncology based on the gamma delta T cell platform using either previously validated antigens or those that we identify and target using our TCRL technology. We may utilize additional genetic engineering, editing technologies or other technologies with the goal of further improving the activity and safety profile of our product candidates. A key strength of our gamma delta T cell therapy platform lies in our ability to target antigens of both known and unknown potential and devote our clinical development resources to those antigens that show the most promise in preclinical *in vivo* analyses and early human trials.
- **Expand and protect our intellectual property.** We will continue to aggressively protect the gamma delta T cell production methodology we have developed as well as specific product candidates based on proprietary antigen-binding domains. For more information on our intellectual property, see “*Adicet Business— Our Intellectual Property*” on page 26 of this Annual Report on Form 10-K.

Background

Anticancer immune cell therapy

In recent years, the field of immuno-oncology has transformed the treatment of cancer. Immuno-oncology deploys the immune system to attack and, in some cases, to eliminate cancer. One of the key breakthroughs in immuno-oncology involved using T cells, a key element of the immune system, and turning them into even more potent, tumor-cell-specific killers. Researchers have achieved this improvement and targeting by loading the T cells with a gene encoding a CAR. These engineered receptors represent a powerful combination of, first, a region that binds to a target on a cancer cell and tethers the T cell to it; and second, a signal that activates the T cell to eliminate the tethered cancer cell. To our knowledge, all marketed CAR-T cells contain predominantly alpha beta T cells. While we believe the use of CAR-T cell therapies is extremely promising, conventional CAR-T cell therapies also have some key flaws that, we believe, can potentially be addressed by using a cell population, specifically, gamma delta T cells rather than alpha beta T cells.

As of March 10, 2021, four CD19-targeting CAR-T cell therapies have been approved by the FDA: axicabtagene ciloleucel (Yescarta®) and brexucabtagene autoleucel (Tecartus™) developed by Kite Pharma (now Gilead); tisagenlecleucel (Kymriah®), developed by Novartis; and lisocabtagene maraleucel (Breyanzi®) developed by Juno Therapeutics, Inc. (now Bristol Myers Squibb Company). These therapies are highly effective in many patients. Among the 101 patients with diffuse large B cell lymphoma, or DLBCL, treated with Yescarta® in a clinical trial, an objective response rate of 82% was observed with 54% of patients achieving a complete response. This high efficacy, however, is associated with significant adverse events, with 13% of patients experiencing grade 3 or higher cytokine release syndrome and 28% of patients experiencing grade 3 or higher neurologic events. In the Yescarta® DLBCL clinical trial, three patients died due to adverse events during treatment and ten patients who were enrolled in the trial were not able to be treated due to disease progression or complications that arose during the period of time required to generate the patient-specific therapy or because of the inability to generate the desired CAR-T cells from the patient’s cells. Despite these known adverse events, in 2017 and 2018, leading CAR-T cell companies Kite Pharma and Juno Therapeutics, Inc., or Juno, were acquired for a total of \$20.9 billion by Gilead and Celgene, now Bristol Myers-Squibb, respectively. We believe these acquisitions were a result of a combination of the ability of Kite Pharma and Juno to treat cancer immediately through the initial product candidates and projected to generate numerous additional candidates. We believe that, despite their progress to date, currently available CAR-T cell therapies have not reached their full promise, and our gamma delta CAR-T cell approach has the potential to be a significant improvement.

The current generation of CAR-T cell therapies represented by Yescarta®, Tecartus™, and Kymriah® are autologous cell therapies, that is, they are based on immune cells isolated from a patient, modified and expanded in a laboratory and then reintroduced into the same patient. One key reason for taking this autologous approach is that the cytotoxic (cell-killing) predominantly alpha beta T cells that are used to generate these therapies are cells that the immune system uses to recognize and attack foreign cells. If these types of T cells were to be introduced into a patient from an unrelated donor, the donor T cells would attack healthy tissues throughout the patient in a process known as graft versus host disease (GvHD) potentially causing multiple organ failure and death.

The T cells used for first-generation CAR-T cell therapies were derived from a highly abundant subclass of T cells known as alpha beta T cells. Alpha beta T cells, which comprise approximately 95% of the T cells in circulation in the body, are able to distinguish whether cells that they encounter are normal cells that belong in the body or foreign or damaged cells that need to be destroyed. Alpha beta T cells have a receptor on their surface called a TCR which is made up of alpha and beta protein chains. These TCRs recognize targets, also known as antigens, on cells that are presented by antigen-presenting molecules encoded by the major histocompatibility complex (MHC). The MHC contains genes that encode a number of proteins with multiple variants (alleles), such that most individuals have a distinct MHC profile. During normal T cell development, those T cells that recognize the combination of the specific MHC profile and antigens that are presented by healthy cells of the specific individual are eliminated, resulting in a population of T cells that circulate throughout the body, vigilantly checking for abnormal antigens or foreign cells, including from another individual.

In one type of cellular immunotherapy known as adoptive cell therapy, naturally occurring immune cells from a patient are isolated and are activated using cytokines and tumor-specific antigens to stimulate the growth and expansion of antitumor T cells that already exist at low abundance in the patient. After activation and expansion in the laboratory, large numbers of T cells that are primed to recognize the tumor are reintroduced into the same patient.

CAR-T cell therapies are a variant of this adoptive cell therapy in which, instead of trying to activate T cells based on the ability of naturally occurring TCRs to recognize tumor antigens, a chimeric antigen receptor, or CAR, that is designed to recognize a specific tumor antigen is genetically introduced into T cells. These CAR-T cells are then able to destroy any cells expressing the appropriate antigen completely independent of MHC. However, without further genetic engineering, CAR-T cells derived from alpha beta T cells still have endogenous TCRs which restrict their use to the original patient.

Limitations of autologous cell therapies

Autologous cell therapies, such as those developed by Kite Pharma and Novartis, have a number of limitations, including but not limited to the following:

- **Treatment delays imposed by individualized manufacturing.** Due to the individualized manufacturing process, patients must wait up to three to four weeks for the individualized products to be manufactured and administered. In the registrational trials for Yescarta® and Kymriah®, up to 31% of intended patients ultimately did not receive treatment primarily due to complications from the underlying disease that occurred during manufacturing or due to manufacturing failures.
- **Manufacturing variability and failure.** It was reported by Novartis in 2018 that variability in product specifications had been observed in the production of Kymriah®. In addition, in approximately 9% of the cases, no product could be shipped to patients at all due to out-of-specification issues or from manufacturing failures.
- **High cost limits patient access.** The high cost of therapy and payer policies can limit access to autologous CAR-T cell therapies. According to a 2019 article published in the journal *Managed Care*, treating physicians estimate that the costs of autologous CAR-T cell therapies combined with patient care services are approximately \$1 million per patient, generating reluctance of payers to approve these therapies for patients before they have exhausted other options. These therapies are then relegated to the most heavily pretreated patients who may be unable to withstand the severe side effects.
- **Scalability.** Because each patient requires a custom manufacturing batch, the production of autologous CAR-T cells at the scale needed to meet commercial demand and anticipated label and geographic expansions may be challenging.

Autologous cell therapies, such as CAR-T cells derived from alpha beta T cells, have been successful in their initial use in hematological malignancies. Furthermore, they have provided critical data that demonstrates the potential of immunocellular cancer therapies. However, manufacturing of these cells imposes some critical limitations that could be minimized if similar allogeneic cell therapies that can be given to any patient, regardless of the donor of cells, are developed. We believe that allogeneic cell therapies offer great promise for optimizing the access to therapy, overcoming manufacturing-related and cost-related limitations of autologous cell therapies.

Gamma delta T cells and their allogeneic potential

Gamma delta T cells are a subset of T cells that have TCRs comprising gamma and delta receptor chains. In contrast to alpha beta T cells, gamma delta T cells are not selective for patient-specific MHC molecules. Therefore, gamma delta T cells from an unrelated donor can be administered to a patient without inducing GvHD and may recognize tumor-associated antigens in an MHC-independent manner. Gamma delta T cells primarily reside in tissues and comprise between 1% and 5% of circulating T cells.

Gamma delta T cells correlate with improved outcomes

An analysis of the transcriptional profiles of 5,872 patient tumor samples across 25 malignancies published in *Nature Medicine* in 2015 found that gene signatures consistent with gamma delta T cells were the strongest predictors of overall survival. The association of gamma delta T cells with overall survival in solid tumors had a z-score over three, meaning it was over three standard deviations above the mean, corresponding to a p value less than 0.001.

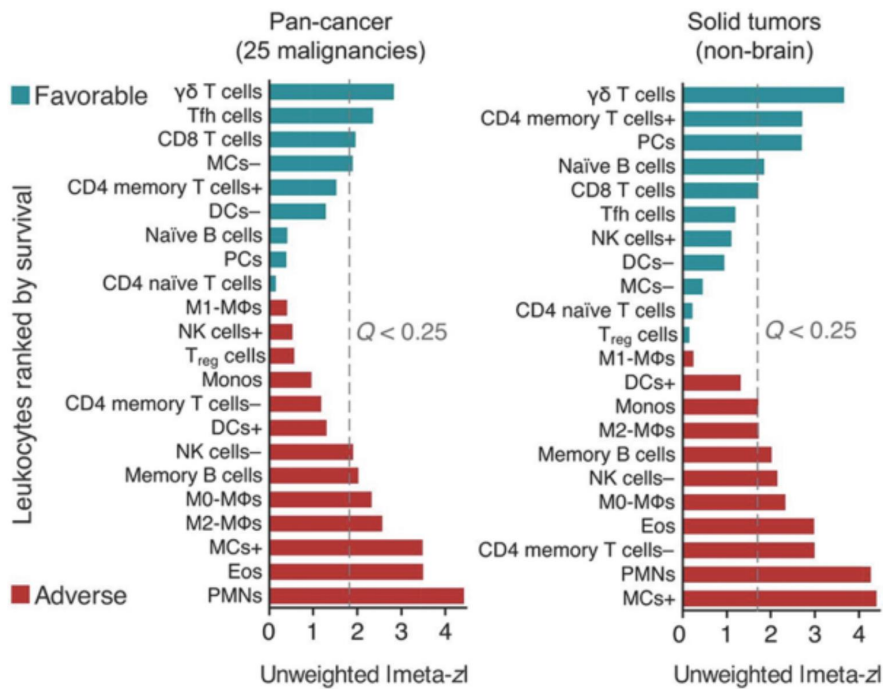


Figure 1. Analysis of the immune cell composition of tumor samples that gamma delta T cells were highly predictive of overall survival. Adapted from Gentles et al., Nat Med. 2015; 21(8).

Additionally, high levels of gamma delta T cells have been associated with improved overall survival in acute leukemia patients who received hematopoietic stem cell transplants (HSCT). In a study published by KT Godder et al. in 2007 in the journal *Bone Marrow Transplantation*, those patients with high levels of gamma delta T cells after the transplant had a leukemia free survival at five-years of 54.4% and overall survival of 70.8%. Those with low levels of gamma delta T cells had a significantly lower five-year leukemia free survival of 19.1% and a five-year overall survival of 19.6%.

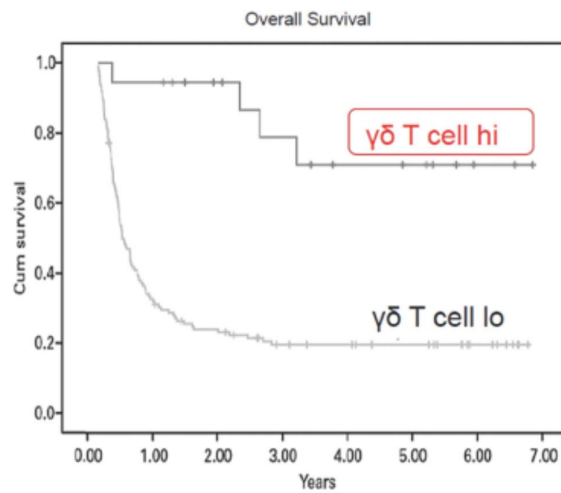


Figure 2. HSCT patients who develop high levels of gamma delta T cells have improved survival. Adapted from Godder et al., *Bone Marrow Transplantation* 2007; 39.

The correlation between high levels of gamma delta T cells and disease-free survival extends to patients with solid tumors. In a study published by Meraviglia et al in 2017 in the journal *Oncoimmunology*, across a cohort of 557 patients with colorectal cancer, those with high gamma delta T cell levels had a five-year disease-free survival rate of over 80%, and revealed that DFS probability was significantly higher in CRC patients with high number of tumor infiltrating gamma delta T cells.

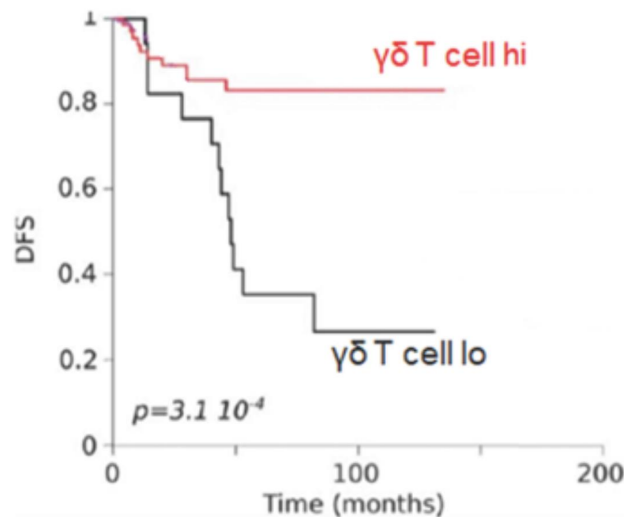


Figure 3. High levels of gamma delta T cells are correlated with increased disease-free survival in colorectal cancer patients. Adapted from Meraviglia et al., *Oncoimmunology* 2017; 6 (10).

We believe that these studies and others point to an important role of gamma delta T cells in disease control and overall survival and indicate that gamma delta T cell-based therapies have the potential to deliver clinically meaningful results.

Advantages of gamma delta T cell-based therapies

Immunotherapies developed using gamma delta T cells have a number of advantages over other therapies developed using other cell types, including the following:

- **Lack of GvHD.** A body of published evidence, mainly in the field of HSCT, supports the safety profile of transfer of allogeneic gamma delta T cells from donors to unrelated patient recipients. HSCT procedures containing significant numbers of gamma delta T cells were able to proceed with no signs of acute or chronic GvHD. In many cases, the presence of gamma delta T cells in the HSCT products correlated with improved clinical outcomes, indicating the antitumor potential of gamma delta T cells. Additionally, a study performed by Martin Wilhelm and colleagues in 2014 indicated that gamma delta T cells from haploidentical donors could be successfully expanded and infused in large numbers (2.17×10^6 cells / kg (range, 0.9-3.84)), followed by further expansion (mean, 68-fold) in the patients without any observed GvHD.
- **MHC-independent tumor antigen recognition.** Gamma delta TCR can recognize tumor associated antigens in a MHC-independent manner, facilitating the use of products derived from healthy donors who are unrelated to patients which may avoid the need to match the HLA-type of the donor to the patient.
- **Tumor localization.** In addition to being present in the circulation at low frequency, gamma delta T cells have an inherent propensity to home to tissues and tumors. Their ability to be activated in environments with low levels of oxygen such as those found in the tumor microenvironment has the potential to increase the activity of gamma delta T cells in solid tumors.
- **Limited cytokine secretion.** Unlike alpha beta T cells, gamma delta T cells can be made to secrete lower levels of certain cytokines such as interleukin 2 (IL-2). This, combined with lack of recognition of normal, non-malignant, cells by gamma delta T cells, may lower the risk of life-threatening cytokine release syndrome.
- **Limited ability for tumors to escape.** Although the initial responses to immunotherapies such as antibodies and CAR-T cells are often impressive, many patients become refractory or relapse. A common mechanism for the relapse to these therapies is loss of the expression of the CAR-targeted antigen such as CD19 from tumor cells. Because gamma delta T cells also express innate cytotoxic immune receptors, they can recognize and kill tumor cells even in the absence of the CAR-targeted tumor antigen.
- **Ability to manufacture more efficiently and cost-effectively.** Unlike alpha beta T cells, therapies based on gamma delta T cells can potentially be manufactured in bulk and used in the allogeneic or off-the-shelf setting, addressing many of the shortcomings of conventional alpha beta T cell therapy.
- **Potential for superior cytotoxic activity.** T cells from some cancer patients, for example those with chronic lymphocytic leukemia, often display an exhausted, or otherwise dysfunctional, phenotype and CAR-T cell products from these cells may perform poorly. Our allogeneic cell therapy is manufactured from healthy donors whose T cells have been proven to generate highly active CAR-T cell product.
- **Potential for re-dosing.** Along with increased availability of material due to the ability to utilize off-the-shelf healthy allogeneic donor-derived starting material compared to conventional CAR-T cell therapies, the lack of MHC-dependent GvHD also opens up the possibility of being able to re-dose patients to achieve further clinical activity if they do not obtain an adequate clinical response from initial treatment or if they relapse. A number of studies with other CAR-T cell therapies have linked the development of cytokine release syndrome with high numbers of circulating CAR T cells following rapid alpha beta T cell proliferation. Having the option to retreat patients with gamma delta T cells provides the option of starting with a low dose and redosing if required.

Our CAR gamma delta T-cell technology

Human gamma delta T cells can be divided into three main subsets based on their TCR delta chain usage: V δ 1, V δ 2 and V δ 3. The most abundant subset of gamma delta T cells in the circulatory system, the V δ 2 cells, is the most well-studied. However, it is the V δ 1 subset which primarily resides in tissues and presents a favorable cytotoxic anti-tumor profile that we are activating and manufacturing using our proprietary platform technology.

Vδ1 gamma delta T cells

Vδ1 cells have properties of both the innate and adaptive immune system, meaning that they can be activated by tumor-specific antigens as well as by general activators common to damaged or otherwise abnormal cells. Similar to other T cells, they express TCRs, but also express cytotoxicity receptors that are found on innate immune cells such as natural killer (NK), cells. These gamma delta T cells can induce tumor cell death through multiple mechanisms including the secretion of cytotoxic proteins such as granzymes and perforin as well as through the secretion of cytokines such as interferon gamma (IFNγ), and tumor necrosis factor alpha (TNFα).

In *in vitro* and *in vivo* preclinical cancer models, Vδ1 cells are more cytotoxic and may have a longer durability than Vδ2 cells. Vδ1 cells are also more resistant to activation induced cell death (AICD), which has posed significant problems in clinical trials following chronic stimulation of Vδ2 cells. Vδ1 cells normally reside within tissues and they are able to adapt to lower nutrient availability and decreased oxygen levels, conditions which are similar to those in the microenvironments or localized areas associated with certain solid tumors. Incubation of these gamma delta T cells in conditions of low oxygen (hypoxia) that are typical of tumors has been shown to enhance their cytotoxicity.

Anticipated advantages of Vδ1 gamma delta T cells over NK cell based therapies

An alternate approach to the development of allogeneic CAR T cells consists of engineered natural killer (NK), cell-based therapy. While both gamma delta T cell and NK cell therapy generally are not expected to cause graft versus host disease, NK cells express a broad repertoire of both inhibitory and activating receptors and have more limited tumor induced secretion of multiple cytokines. We believe that the gamma delta T cell technology it uses has several advantages over this approach. Unlike engineered NK cells, Vδ1 gamma delta T-cells have the following advantages:

- The presence of gamma delta cells in tumors is strongly correlated with positive clinical outcomes;
- Can display tumor-induced secretion of multiple cytokines including expressing high levels of interferon-gamma;
- Can be produced as highly homogeneous cell populations that display potent non-clinical anti-tumor activity;
- Express activating receptors more predominantly;
- Display features of adaptive immunity including, TCR-mediated, but MHC-independent, tumor antigen recognition, a long lifespan and persistence for protracted periods of time;

We believe these advantages position gamma delta T cell-based therapies to become an attractive alternative to NK based therapies for many oncology indications and lines of therapy.

Anticipated advantages of Vδ1 gamma delta T cells over other approaches to generate allogeneic CAR-T cells

An alternative approach to the development of allogeneic gamma delta CAR T cells consists of introducing genetic modifications that disable the TCR in alpha beta T cells derived from donors that are not related to the patient. This process prevents these cells from attacking the patient's healthy cells. We believe that the healthy donor-derived gamma delta T cell technology, which lacks the ability to attack healthy cells from unrelated individuals, has a number of advantages over this approach. In an allogeneic paradigm, unlike alpha beta T cells, Vδ1 gamma delta T-cells have the following advantages:

- Do not rely on genetic manipulations to inactivate the alpha beta TCR;
- Display properties of both adaptive and innate immune systems and are capable of killing cells even if their specifically targeted CAR antigen is expressed at low levels or not present;
- May not be prone to exhaustion and are likely to persist longer;
- May maintain the capacity to home to tissues and tumors rather than predominantly residing in circulation; and
- May be less likely to induce cytokine release syndrome due to more limited endogenous IL-2 secretion by activated cells.

We believe these advantages position gamma delta T cell based therapies to become an attractive alternative to alpha beta T cell based therapies.

Anticipated advantages of Vδ1 gamma delta T cells over bispecific antibody T cell recruitment for tumor immunotherapy

An alternative approach to the development of allogeneic CAR T cells consists of bispecific antibodies that are designed to crosslink T cells to specific targets on the tumor. This approach generally requires healthy and functional T cells able to attack the tumor when guided to the tumor expressing the target antigen. We believe that the healthy donor-derived gamma delta T cell technology has a number of potential advantages over this approach. Unlike bispecific antibodies, Vδ1 gamma delta T cells have the following advantages:

- Do not rely on functional T cells derived from the patient for clinical activity;
- Display properties of both adaptive and innate immune systems and are capable of killing cells even if their specifically targeted CAR antigen is not present;
- Maintain the capacity to home to tissues and tumors rather than predominantly residing in circulation and can actively distribute into localized tumors; and
- May be less likely to induce cytokine release syndrome due to more limited endogenous IL-2 secretion by activated cells.

We believe these advantages position gamma delta T cell-based therapies to become an attractive to bispecific-based therapies for many oncology indications and lines of therapy.

Our key anticipated differentiation from gamma delta T cell competitors

We believe that the gamma delta T cell technology that it is developing has a number of potential advantages over the technology of gamma delta T cell competitor companies, including the following:

- Robust and practical proprietary antibody-based manufacturing method for gamma delta T cells
- Large-scale expansion of blood-derived gamma delta T cells
- Ability to selectively expand multiple gamma delta T cell subpopulations including highly potent Vδ1 cells
- No potentially pro-tumorigenic Th17-type responses in our Vδ1 subpopulation
- In-house chimeric antigen receptor target identification and verification process
- Ability to effectively target tumor-specific intracellular protein-derived peptides using proprietary T cell receptor-like antibodies

We believe these advantages position our gamma delta T-cell based therapies to become an attractive approach to the technologies used by other gamma delta T cell competitor companies.

Production of gamma delta T cells

To produce gamma delta T cell-based product candidates, we isolate peripheral blood mononuclear cells (PBMCs), from healthy donors that meet all the safety criteria for human cells, tissues, and cellular and tissue-based products (HCT/P), criteria for donors as outlined by the FDA in 21 CFR Part 1271. We then activate V δ 1 gamma delta T cells using a proprietary agonistic antibody and cytokines and expands these cells before introduction of replication-incompetent retroviral vectors containing the coding sequence for CAR constructs. These CAR-modified cells are further expanded, routinely greater than 6,000-fold at clinical scale, resulting in cell cultures that primarily consist of the desired gamma delta T cells. To reduce the chance of a patient developing GvHD, the remaining alpha beta T cells are then depleted using alpha-beta-specific, antibody-based techniques. The resulting gamma delta T cells are then formulated in an infusible solution to form the final drug product, which is filled into vials and then frozen to enable delivery of a post-thaw cell dose from each vial of CAR-T cells.

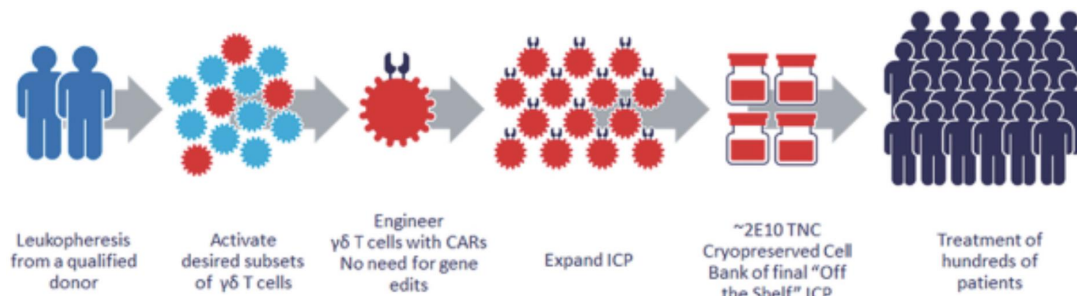


Figure 4. Production process for our CAR gamma delta T cell products.

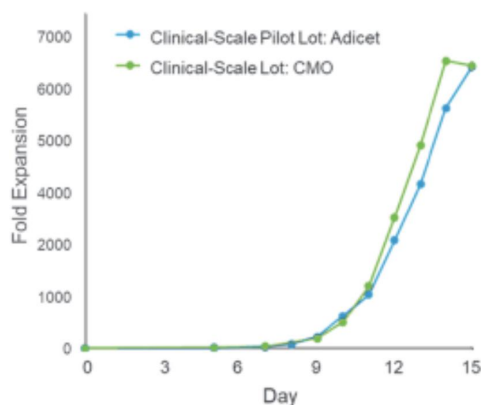


Figure 5. Fold expansion of gamma delta T cells.

We believe that our manufacturing process, including the generation of the antibodies and retroviral vectors, meets current GMPs, i.e. is a cGMP-compliant process. We expect to be able to produce tens to hundreds of doses from a single donor, greatly increasing the efficiency of manufacturing compared to autologous alpha beta T cell therapies. We have chosen to partner with a number of contract manufacturing organizations in the U.S. and Europe to access specific capabilities to ensure that the manufacturing process is highly scalable, and fully cGMP-compliant, and we believe this process has the potential to treat up to 1,000 patients per batch.

ADI-001, an anti-CD20 CAR gamma delta T-cell therapy

ADI-001 is an allogeneic V δ 1 gamma delta T cell product candidate containing an anti-CD20 CAR. We are developing ADI-001 for the treatment of NHL. In October 2020, the FDA cleared our IND application for ADI-001. We expect initial clinical results from this trial in 2021.

B cell NHL overview

NHL is the most common cancer of the lymphatic system. An estimated 77,240 new cases are expected to be diagnosed in the U.S. in 2020, according to the web site of the U.S. National Institutes of Health. According to the cancer.net web site maintained by the American Society for Clinical Oncology, approximately 90% of NHL patients in western countries have B

cell lymphomas of various types and diffuse large B cell lymphoma (DLBCL), is the most common and aggressive type of NHL, accounting for 30% of NHL. The second most common type is follicular lymphoma (FL), which occurs in 20% of NHL patients. Mantle cell lymphoma (MCL), is diagnosed in 5% to 7% of NHL cases.

Although B cell NHLs represent a heterogeneous set of lymphomas, many cell surface antigens are shared among them, including CD19 and CD20. First line therapy for patients with aggressive B cell NHLs, such as DLBCL, is chemotherapy in combination with radiation or rituximab, an antibody that targets CD20. According to the rituximab label as published on the FDA web site, the addition of rituximab to chemotherapy results in an approximately 10% to 15% overall increase in survival at one year compared to chemotherapy alone with almost no increase in toxicity. According to an article published by K.T. Godder et al. in the journal *Bone Marrow Transplantation* in 2007, up to 50% of patients become refractory or relapse after treatment. Of those, according to an article published by Andrew R. Rezvani and David G. Maloney in the journal *Best Practice & Research Clinical Haematology* in 2011, approximately 60% percent are resistant to rituximab upon relapse. Subsequent chemotherapy-based therapies typically have limited efficacy in these patients and, at that point, they become candidates for treatment with allogeneic HSCT or anti-CD19 CAR-T cell therapy. Approximately 35% of patients treated with anti-CD19 CAR-T cell therapies relapse within one year, according to the label for Kymriah® published on the Novartis web site.

Our solution, ADI-001

ADI-001 is a gamma delta T cell product candidate that targets malignant B-cells via an anti-CD20 CAR and via the gamma delta T cell endogenous receptors, which we are developing as an allogeneic immunocellular therapy for the treatment of B-cell NHL. ADI-001 is created from V δ 1 gamma delta T cells isolated from healthy donors. It is manufactured in bulk under cGMP-compliant conditions and is intended to be supplied as an immediately available off-the-shelf anti-CD20 CAR-T cell therapy. In October 2020, the FDA cleared our IND application for ADI-001. We intend to initiate a clinical trial and treat the first patient with ADI-001 in March 2021.

ADI-001 contains an anti-CD20 CAR that has a proprietary antigen-binding domain that recognizes a region of CD20 distinct from that recognized by rituximab. Similar to other CAR-Ts cells including the one used to create Kymriah®, our CAR-T cells contain the clinically validated costimulatory domain from 4-1BB and the CD3 ζ .

Preclinical data

All preclinical experiments were conducted using anti-CD20 CAR-modified gamma delta T cells, a research version of ADI-001. We evaluated the *in vitro* potency of our anti-CD20 CAR gamma delta T cells using human-derived laboratory cell lines, known as Raji and Daudi human Burkitt's lymphoma cell lines, which are known to express high levels of CD20. Mixing the tumor cells with the anti-CD20 CAR gamma delta T cells resulted in apoptosis, or cell death, of the tumor cells after four hours. Increasing the ratio of the number of anti-CD20 CAR gamma delta T cells to tumor cells resulted in a higher percentage of dying tumor cells. Similar potency in the killing of target cells by anti CD20 CAR gamma delta T cells was observed in both Mino cells, a human mantle cell lymphoma line that expresses high levels of CD20; and WILL-2 cells, cells derived from a rituximab-resistant patient with B cell lymphoma that expresses low levels of CD20. These results suggest that anti-CD20 CAR gamma delta cells can be highly efficient at recognizing and eliminating tumor cells that express any level of CD20. In all the cases, our gamma delta T cells that did not have anti-CD20 CAR expression also caused tumor cell death due to innate cytotoxic receptors.

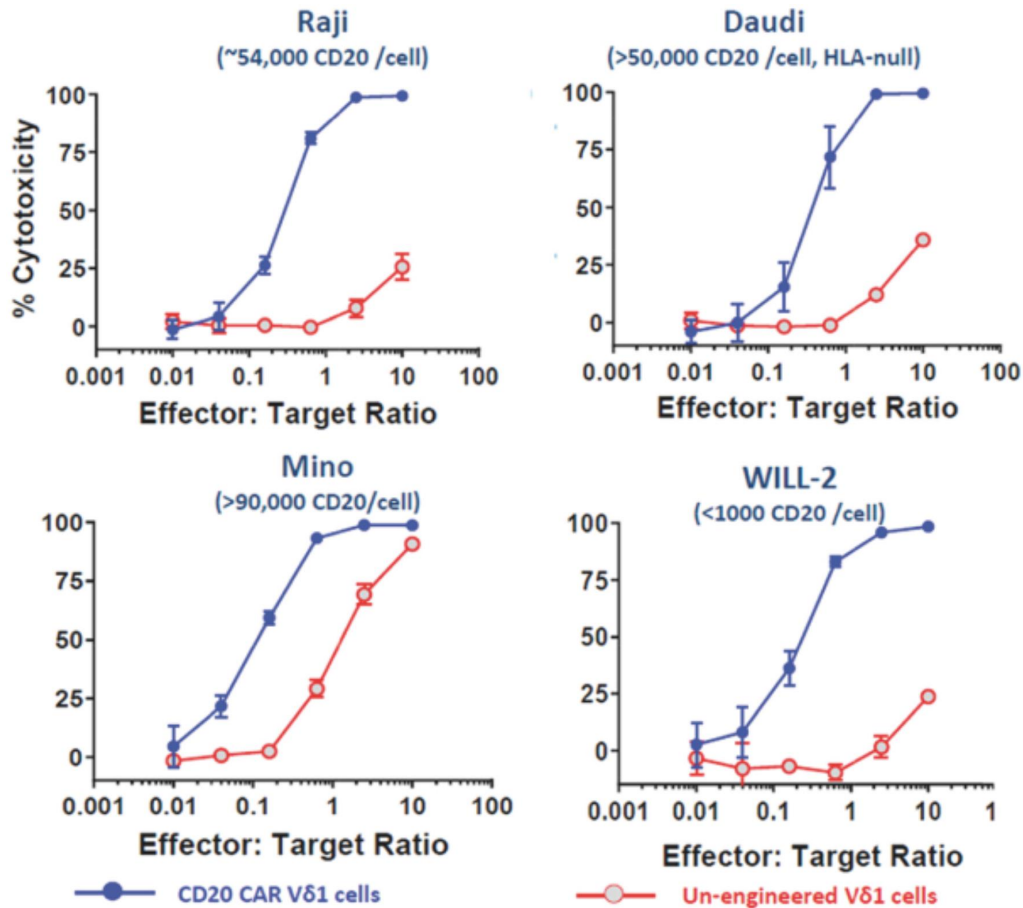


Figure 6. Anti-CD20 CAR gamma delta T cells demonstrated potent cell killing activity across multiple human tumor cell lines.

We have tested the antitumor activity of our anti-CD20 CAR gamma delta T cells in multiple tumor models in immunocompromised mice including Raji tumor models, a Mino tumor model and a Granta tumor model derived from a mantle cell tumor. Five to seven days after tumors were implanted into these mice, anti-CD20 CAR gamma delta T cells were administered as a single intravenous dose. Human recombinant IL-2 was administered three times a week for the duration of the study to stimulate the gamma delta T cells. In all cases, treatment using our anti-CD20 CAR gamma delta T cells was able to arrest tumor growth. The absolute duration of these studies was not pre-specified, however each of the studies were terminated when the growth of tumors in any of the animals in the no-treatment control group (tumor-only) exceeded a pre-specified limit; in subcutaneous tumor models this limit was generally tumor growth exceeding 4000mm³. This resulted in the individual studies being run for slightly different durations.

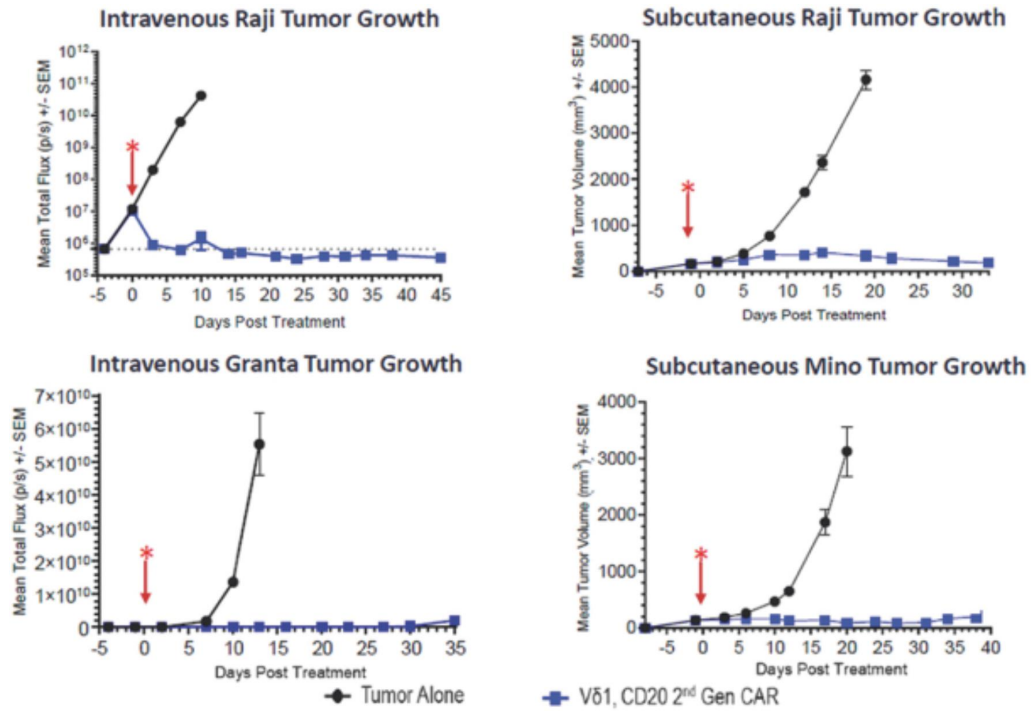


Figure 7. Anti-CD20 CAR gamma delta T cells inhibited tumor growth in multiple animal models.

Treatment of Raji tumors in mice with anti-CD20 CAR gamma delta T cells resulted in the complete elimination of tumors in four out of six mice. Sixty days after the original — and only — dose of anti-CD20 CAR gamma delta T cells, the four mice with complete responses were re-challenged with Raji tumor cells. Growth of these newly introduced tumors continued to be suppressed at least until the end of the experiment at day 100. We believe that these results suggest that our gamma delta cells had a long persistence *in vivo* and remain active. Other preclinical experiments have shown that they can undergo up to twenty cell doublings and can have antitumor activity that can extend to six months in animal models.

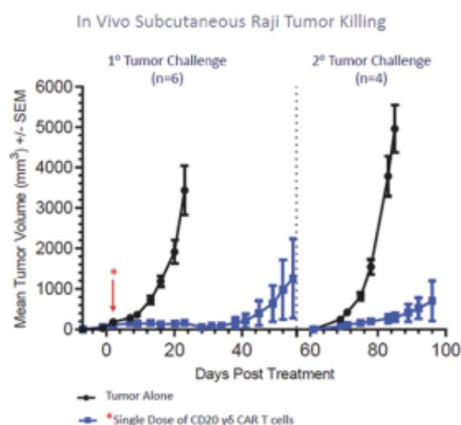


Figure 8. Gamma delta T cells retained their antitumor activity for at least 90 days in a Raji tumor model. Four of the six mice in the primary tumor challenge exhibited complete responses, and these four mice were given a second tumor challenge without additional gamma delta CAR T cells.

We performed a direct analysis of the ability of our gamma delta CAR-T cells to migrate and proliferate in tumors using a fluorescent dye technology to examine cell division. Gamma delta CAR-T cells were treated with a fluorescent dye that attaches to cellular proteins. As these fluorescent cells divided, the molecules modified with the fluorescent dye were split among the mother and daughter cells. This resulted in a reduction in the average fluorescence signal per cell. Quantification of the amount of fluorescence per cell was then used as a surrogate for the number of divisions that a cell has undergone.

Using this assay, we observed that, within six days, our CAR gamma delta T cells had undergone significant cell divisions in tumors with little replication in blood, spleen, bone marrow or liver. By contrast, in a similar experiment using CAR alpha beta T cells, it was observed that replication occurred in all tissues examined. We believe that this selective replication in tumors by CAR gamma delta T cells, compared to CAR alpha beta T cells, may contribute to increased antitumor activity and a lower risk of developing life-threatening systemic immune responses such as cytokine release syndrome.

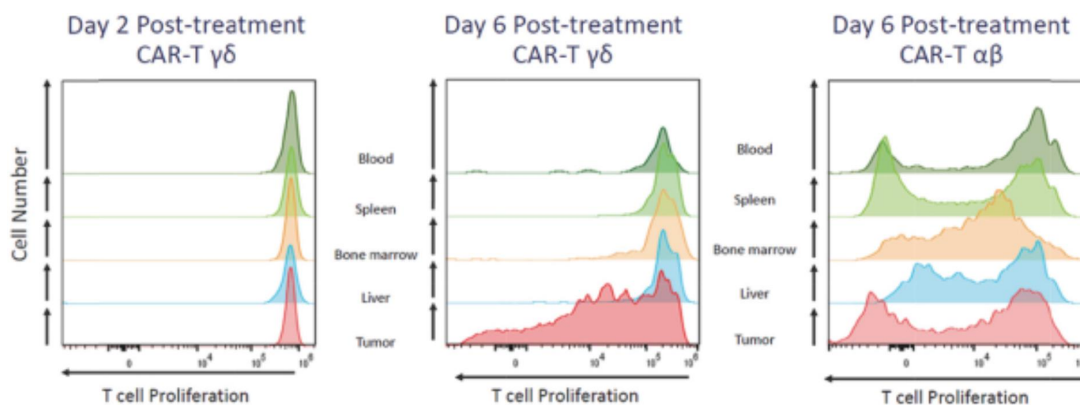


Figure 9. Proliferation of CAR gamma delta T cells was primarily localized in tumors, while the proliferation of CAR alpha beta T cells was observed in all tissues examined.

Interleukin 15 (IL-15) is a cytokine that preferentially stimulates T cell and NK cell activation, proliferation and cytolytic activity. These functional activities of IL-15 translate to enhanced antitumor responses in multiple tumor models. IL-15 is closely related to a cytokine that is a known activator of immune responses, IL-2. Both cytokines have the potential to

stimulate gamma delta T cells. IL-15 plays a more important role in maintaining T cell responses that are long-lasting and show high affinity for cancer cell targets, while IL-2 has a more significant role in activating cytotoxic responses.

The antitumor activity of our anti-CD20 CAR gamma delta T cells was tested in SRG-15 mice. These are mice that lack much of their mouse immune system but that do express human IL-15. In these studies, potent antitumor activity against Raji tumors in was observed. Furthermore, this activity was not accompanied by the development of GvHD. In contrast, mice treated with anti-CD20 CAR alpha beta T cells had antitumor responses, but subsequently experienced increased mortality due to the development of GvHD.

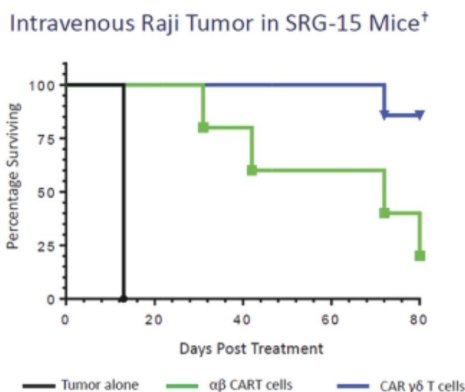


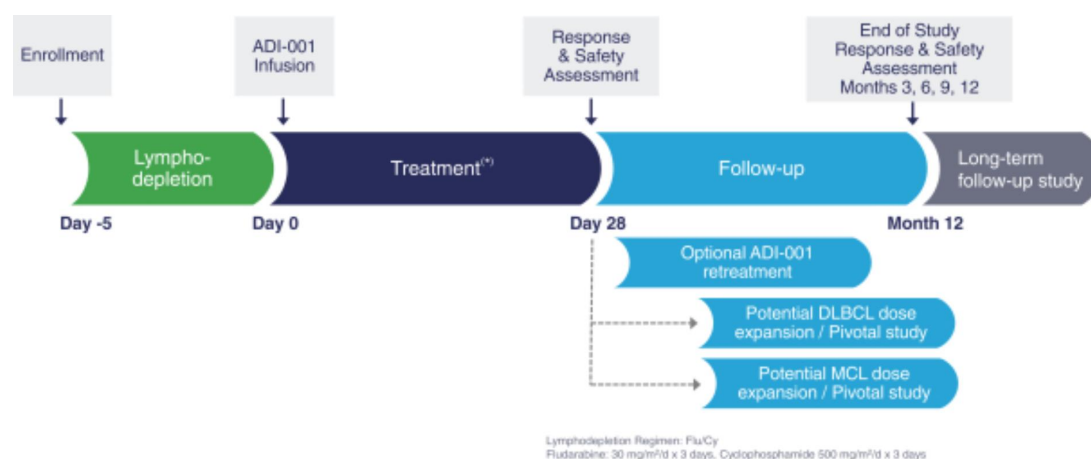
Figure 10. Anti-CD20 CAR gamma delta T cells do not induce GvHD, whereas treatment with anti-CD20 CAR alpha beta cells caused GvHD that led to increased mortality.

ADI-001 clinical plans

In October 2020, the FDA cleared our IND application for ADI-001 for the treatment of NHL. The active IND enables us to initiate the first-in-human clinical trial to assess safety and efficacy of ADI-001 in NHL patients in the first quarter of 2021. The Phase 1 study for ADI-001 will enroll up to 80 late-stage NHL patients at a number of cancer centers across the U.S. The study includes a dose finding portion followed by dose expansion cohorts to explore the activity of ADI-001 in multiple subtypes of NHL. Included in this trial will be previously treated patients that were not able to receive approved autologous CAR-T cell therapies due to medical, technical, logistical, or financial reasons, as well as patients who relapsed after receiving autologous CAR-T cell therapies. Site initiation activities are underway and interim clinical data from this study are expected in 2021.

Patients enrolled in the trial will undergo chemotherapy-based lymphodepletion for three days followed by ADI-001 dosing by infusion on day five. Patients will be evaluated at four weeks, twelve weeks and then every three months for the first year and at months 18 and 24 after treatment. Once a recommended dose has been selected, up to 36 patients will be enrolled in indication-specific dose expansion cohorts: DLBCL, MCL, and one for all other B cell malignancies. Select patients experiencing clinical benefit with ADI-001 may be eligible for retreatment.

An additional cohort in this trial will investigate the potential of IL-2 therapy to boost the activity and durability of ADI-001. Treatment with IL-2 is supported by preclinical data that we have generated demonstrating that IL-2 improves the antitumor activity of our gamma delta T cells both *in vitro* and *in vivo*. Treatment of HSCT patients with IL-2 has also been shown to stimulate the proliferation of gamma delta T cells in the clinic.



(*) Dose escalation study

Figure 11. Phase 1 study patient flow.

ADI-002, an anti-GPC3 CAR gamma delta T-cell therapy

ADI-002 is a gamma delta T cell containing a CAR that is specific for glypican 3 protein (GPC3), a protein that is highly expressed on the surface of multiple solid tumors including hepatocellular carcinoma (HCC), gastric cancer, and squamous cell carcinoma of the lung (SCCL). We intend to file an IND application with the FDA in late 2021 for ADI-002. Subject to the FDA regulatory process for review of INDs, we intend to initiate a clinical trial and treat the first patient with ADI-002 in 2022.

HCC disease background

Hepatocellular carcinoma (HCC) is the most prevalent form of liver cancer. The risk of HCC development is increased by a number of environmental and lifestyle factors such as hepatitis B and hepatitis C virus, alcohol drinking, tobacco smoking, aflatoxin exposure, obesity and diabetes. These factors lead to wide disparities in disease incidence across geographies. According to a 2013 publication by Sahil Mittal and Hashem B. El-Serag in the *Journal of Clinical Gastroenterology*, in the U.S., the incidence is approximately six per 100,000 per year, while in sub-Saharan Africa and Eastern Asia the incidence is over 20 per 100,000 per year.

Patients diagnosed with HCC generally have a poor prognosis. The majority of patients are diagnosed with advanced disease and they have a five-year survival rate of approximately 11%, according to cancer.net, the web site of the American Society of Clinical Oncology. Patients are initially treated with combinations of cytotoxic drugs or radiation. In some cases, they may also receive targeted therapies including kinase inhibitors such as lenvatinib, marketed as Lenvima® by Eisai; and sorafenib, marketed as Nexavar® by Bayer and subsequently cabozantinib, marketed as Cabometyx® by Exelixis. These therapies, however, have significant toxicities and limited clinical benefit with progression free survival of less than eight months. Checkpoint immunotherapies such as pembrolizumab and nivolumab have demonstrated some efficacy in HCC, although response rates are less than 20% according to the label for pembrolizumab, marketed by Merck as Keytruda®. The combination of both nivolumab and ipilimumab, despite increased toxicities, increased this response rate to 33%. We believe these results demonstrate that there is significant unmet need in HCC and that there is potential to treat HCC with immunotherapy.

GPC3, a tumor-associated antigen

GPC3, is a tumor-associated antigen that is expressed in many tumors but in almost no normal tissues other than embryonic liver and kidney or placenta.

Glypican 3 Expression in Tumors*

Tumor Entity	No. (%) Staining		
	No. of Cases	Negative	Positive
Hepatocellular carcinoma	44	15 (34)	29 (66)
Squamous cell carcinoma of the lung	50	23 (46)	27 (54)
Liposarcoma	29	14 (48)	15 (52)
Testicular nonseminomatous germ cell tumor	62	30 (48)	32 (52)
Cervical intraepithelial neoplasia (grade 3)	29	17 (59)	12 (41)
Malignant melanoma	48	34 (71)	14 (29)
Adenoma of the adrenal gland	15	11 (73)	4 (27)
Schwannoma	46	34 (74)	12 (26)
Malignant fibrous histiocytoma	29	22 (76)	7 (24)
Adenocarcinoma of the stomach (intestinal subtype)	45	36 (80)	9 (20)
Chromophobe renal cell carcinoma	15	12 (80)	3 (20)
Invasive lobular carcinoma of the breast	46	37 (80)	9 (20)
Medullary carcinoma of the breast	30	25 (83)	5 (17)
Squamous cell carcinoma of the larynx	49	41 (84)	8 (16)
Small cell carcinoma of the lung	49	41 (84)	8 (16)
Invasive transitional cell carcinoma of the urinary bladder	43	36 (84)	7 (16)
Mucinous carcinoma of the breast	26	22 (85)	4 (15)
Squamous cell carcinoma of the cervix	41	35 (85)	6 (15)

Figure 12. Screening of a panel of over 4,000 tumor samples found that GPC3 is expressed in numerous cancers. Baumhoer et al., Am. J. Clin. Pathol. 2008;129.

In a trial conducted by David Ho at the University of Hong Kong and colleagues and published in the journal *PLoS One* in 2012, high levels of GPC3 are detected by immunohistochemistry in a large proportion of HCC tumor tissue samples, but no GPC3 can be detected in adjacent normal cells.

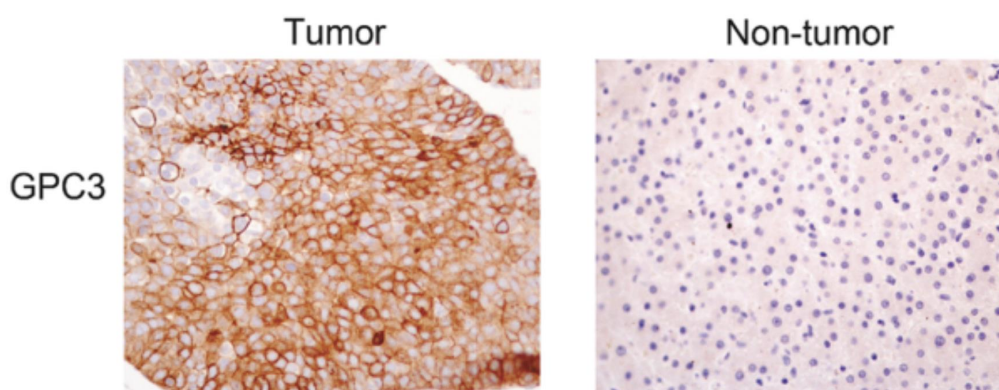


Figure 13. Immunohistochemistry detected strong signals of GPC3 in liver tumor tissue, but negative staining for GPC3 was detected in the adjacent non-tumorous tissue. Adapted from Ho et al., PLoS One. 2012;7(5).

Our solution, ADI-002

ADI-002 is an anti-GPC3 CAR gamma delta T cell product candidate that we are developing for the treatment of solid tumors. We believe that modification of V γ 1 gamma delta T cells, which have an inherent tumor homing ability, with a CAR that is specific for GPC3, may result in a therapeutic product able to have potent antitumor activity in patients suffering from multiple solid tumors. We intend to file an IND application with the FDA in late 2021 for ADI-002. Subject to the FDA regulatory process for review of INDs, we intend to initiate a clinical trial and treat the first patient with ADI-002 in 2022.

To enhance the proliferative ability and durability of our anti-GPC3 CAR gamma delta T cells, we engineered these cells to express soluble IL-15. We anticipate that the tumor homing ability of gamma delta T cells will potentially result in expression of IL-15 predominantly in tumors. In combination with the inherent secretion of factors such as interferon gamma

from activated gamma delta T cells, the secretion of IL-15 is anticipated to lead to reversal of immunosuppressive effects in the tumor microenvironment and direct stimulation of the gamma delta T cells.

We demonstrated in *in vitro* assays that our anti-GPC3 CAR gamma delta T cells have potent and GPC3-antigen-dependent cell killing activity. When our anti-GPC3 CAR-T cells were added to HepG2 cells, a cell line expressing GPC3 that was derived from a patient with HCC, an increase in tumor cell killing was observed. Gamma delta T cells prepared without the addition of our anti-GPC3 CAR were still able to kill the HepG2 cells, only with less potency at 18 hours. We believe that this CAR-independent killing activity was driven by innate receptors on our gamma delta T cells and that this innate antitumor activity may provide meaningful antitumor clinical activity in cases in which tumors may lose the expression of the targeted GPC3 antigen. Loss of tumor-expressed antigens represents a significant mechanism of escape from antitumor activities from other immunotherapies such as anti-CD19 CAR-T cell therapies. The ability to continue to have antitumor activity driven by the innate immune cell properties of our gamma delta T cells is a distinct advantage compared to alpha beta T cells, which lack this capability. Our gamma delta T cells had no cell killing activity when added to RAT2 normal fibroblasts that do not express GPC3.

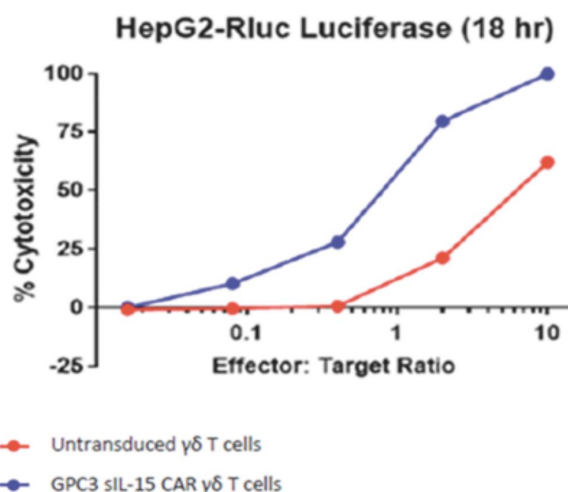


Figure 14. Expression of an anti-GPC3 CAR in gamma delta T cells led to potentiation of killing of HepG2 hepatocellular carcinoma cell line.

Anti-GPC3 CAR gamma delta T cells had dose-dependent antitumor activity in HepG2 tumors in immunodeficient mice. HepG2 tumor cells were inoculated into immunocompromised mice and allowed to grow to a volume of 200 mm³ over a period of approximately eight days. A single dose of anti-GPC3 CAR gamma delta T cells was then administered and tumor growth at day 37 was assessed. High doses of anti-GPC3 gamma delta T cells led to complete suppression of tumor growth.

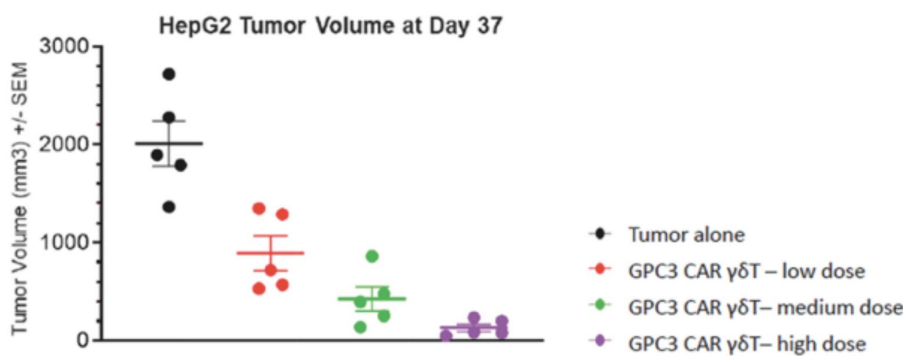


Figure 15. Dose-dependent inhibition of HepG2 tumor growth by anti-GPC3 gamma delta T cells

Future clinical candidates in solid tumors.

In addition to the product candidates described above, we anticipate many further opportunities for developing product candidates based on our gamma delta T cell technology. We believe that the spectrum of indications that products such as CAR-T cell therapies have been able to address has been limited by two factors: the weak ability of alpha beta T cell-based therapies to penetrate solid tumors, and the scarcity of tumor-specific antigens on the cell surface that can be targeted by antibody-derived binding domains that are an essential component of the CAR constructs. We believe that the tumor homing ability of our gamma delta T cell technology represents a potential solution to the solid tumor localization problem and our TCRL antibody technology can be used to identify and target tumor-specific antigens.

The tumor recognition challenge

Therapeutics such as antibodies and CARs recognize cell surface molecules. In HCC and select other tumors, there are proteins such as GPC3 which are selectively expressed on the surface of tumors cells that can be used as antigens for immune-targeted therapy. The lack of their expression on normal cells limits the potential of on-target, off-tumor systemic toxicities. Surface-expressed proteins that are strictly expressed only on tumor cells are, however, rare. In most cases surface expressed antigens such as CD19 and CD20 are expressed both on hematopoietic tumor and normal cells. Therapies that target CD19 or CD20 therefore result in killing of both tumor and normal cells. In hematological malignancies these therapies result in systemic depletion of normal B cells. However, this is mechanism-based toxicity can be managed in clinical practice. Challenges arise with antigens such as epidermal growth factor receptor (EGFR) that is overexpressed on some types of tumor cells, but also expressed on normal epithelial cells elsewhere in the body. Dosing with anti-EGFR antibodies has led to significant dermatological and cardiac toxicities.

Intracellular proteins represent nearly half of the proteins found in human cells. These proteins provide an untapped reservoir of potential tumor-specific antigens that are inaccessible to traditional antibody-binding domains. Immune surveillance for these intracellular proteins is normally done by alpha beta T cells. These intracellular proteins are chopped up by a cell component known as the proteasome into short peptides between eight and ten amino acids long. These short peptides are then presented to the T cells by the MHC. TCRs on the T cells are then able to recognize the complex of the peptide and the MHC, triggering creation of T-cell populations prepared to attack these specific sequences.

Gamma delta T cells have advantages compared to alpha beta T cells with regard to their potential as allogeneic therapies, their ability to localize to tumors and their retention of innate immune signaling pathways. However, to be most effective they need to be able to be engineered to attack specific tumors.

Our solution, TCRLs

We have developed an antibody platform that enables the discovery of TCRL antibodies that recognize peptides that are presented on the cell surface by specific MHC molecules. In effect, our TCRL antibodies have the same antigen recognition properties as TCRs but are highly specific for a single tumor antigen and MHC molecule. They do not recognize other MHC molecules or antigens that may be expressed by healthy cells.

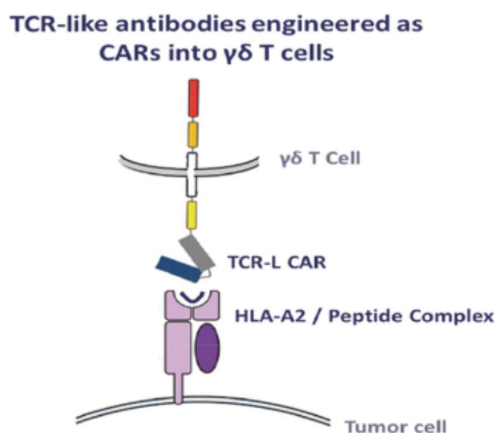


Figure 16. Schematic diagram of the interaction between our TCRL antibodies and tumor-specific peptides presented by the MHC.

TCRLs are conventional antibodies with antigen binding domains that specifically recognize peptide-MHC complexes that can be used to create CARs. Introduction of these CARs into our gamma delta T cells enables them to target tumors expressing intracellular tumor antigens when these antigens are selectively presented by MHC on the surface of tumor cells. Gamma delta CAR-T cells generated using TCRLs open up the potential to bring immune cell therapy to tumors that lack tumor-specific surface antigens, a group that includes most solid tumors.

The TCRL discovery process starts by carrying out an analysis of the peptides expressed by MHC receptors in a panel of hundreds of tumor and normal tissues. In searching for candidate peptides, we focus on differentially expressed peptides that are broadly expressed in tumors but that are not found in normal tissues. Candidate peptides are then validated by expression analysis both in other tissues as well as in databases. Those peptides that, based on bioinformatic analysis, are predicted to have minimal cross-reactivity with peptides from normal cells are then further prioritized. This peptide discovery process leads, step-by-step, to the narrowing of the list of potential candidates by approximately one thousand-fold. Once a tractable number of remaining candidates has been identified, a population that includes the most promising ones, antibodies are then created that are specific to the complex of an MHC receptor and the bound peptides. These antibodies mimic key aspects of tumor as recognized by the immune system. By creating CARs that incorporate these antigen-recognition templates in gamma delta T cell-based product candidates, we create a set of candidates designed to specifically attack tumors by virtue of their intracellular proteins.

Tyrosinase is a well-validated tumor-expressed antigen for which we have developed TCRLs. The specificity for a mouse and a humanized version of one of these TCRLs was determined by comparing their binding affinity to that of a series of peptides that contained single amino acid changes. It was learned that changes to any of the internal eight amino acid positions to the amino acid alanine led to reductions in binding of 70% or greater. Substituting any amino acid in a non-anchor position resulted in substantial loss of binding and indicates the high degree of specificity that the TCRL antibody has for the targeted MHC peptide complex.

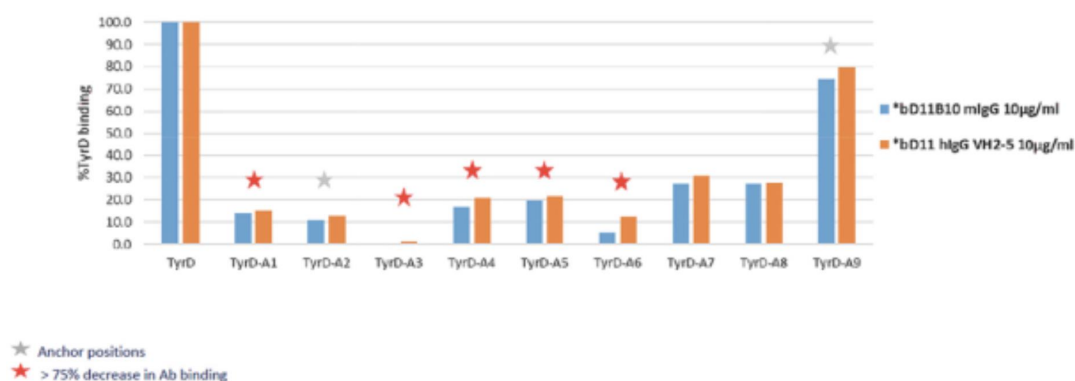


Figure 17. Single amino acid changes to the targeted peptide reduced binding by at least 70 percent.

The antigen-binding domain from a tyrosinase TCRL was incorporated into a CAR and introduced into our gamma delta T cells to assess cell killing activity against tumor cell lines. These anti-Tyr CAR gamma delta T cells led to cell killing of WM266.4 human metastatic melanoma tumor cells, which are known to express tyrosinase. Anti-Tyr CAR gamma delta T cells, however, had no cell killing activity when tested against ten other cell lines from tumors such as colon, bladder and pancreatic cancers, B cell leukemia and retinoblastoma – all of which do not express tyrosinase. That observation points to a desirable level of specificity for our anti-Tyr CAR gamma delta T cells and to an important *in vitro* proof of concept.

Furthermore, these anti-Tyr CAR gamma delta T cells had potent antitumor activity in a WM266.4 tumor model leading to tumor shrinkage within five days of administration and a durable antitumor response through 27 days. Although the TCRL-based CAR that is generated binds to an MHC-peptide complex, it does not induce the GvHD that is seen with alpha beta T cells because it recognizes a single peptide that has been selected to be highly specific for tumor cells.

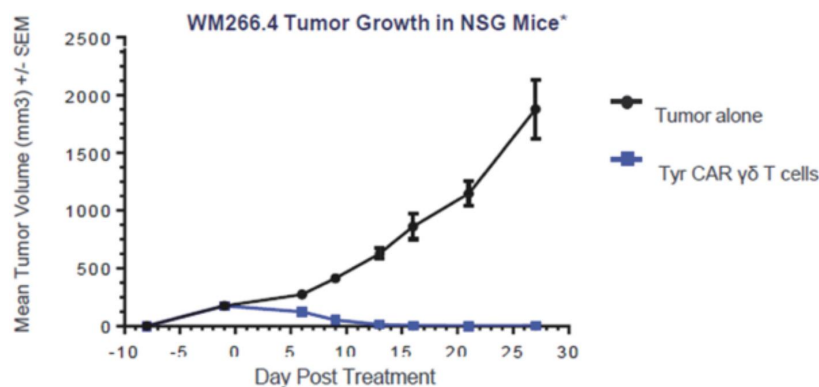


Figure 18. Anti-Tyr CAR gamma delta T cells showed potent antitumor activity in a WM266.4 melanoma model.

We have generated TCRLs against a number of solid tumor antigens which are being evaluating in animal models. We intend to advance at least one candidate from these early-stage programs into IND-enabling studies in 2021. We believe that the combination of our gamma delta and TCRL technology provides the basis for a new generation of CAR-T cell therapies that have the potential to transform the treatment of solid tumors.

Our Intellectual Property

Our gamma delta T cell-based product candidates and substantially all of our intellectual property have been developed by us, with certain antigen binding domains derived from our collaboration with Regeneron. Additional intellectual portfolio assets were acquired via acquisition of Applied Immune Technologies Ltd. in 2016. We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially material to our business, including seeking, maintaining and defending our patent rights.

Our policy is to develop and maintain protection of our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and applications related to our technology, inventions, and improvements that are material to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation, confidentiality agreements, and invention assignment agreements to develop and maintain our proprietary position.

Our patent portfolio includes protection for our lead product candidates, ADI-001 and ADI-002, as well as our other research-stage candidates. As of March 10, 2021, there are multiple patent families comprising three pending U.S. non-provisional applications and over 20 foreign patent applications pending in such jurisdictions as Australia, Canada, China, Europe, Japan, Russia, and South Africa with claims directed to reagents and related protocols for gamma delta T cell expansion and resulting compositions of matter encompassing both ADI-001 and ADI-002, which, if issued, are expected to expire between 2035 and 2037. As of March 10, 2021, there are also two international patent applications (PCT) applications, with claims directed to CAR constructs and antigen binding domains relating to ADI-001 and ADI-002, as well as their methods of use for certain indications, preconditioning methods, and dosing regimens, where applications claiming the benefit of these PCT applications, if issued, would expire between 2038 and 2039. With respect to ADI-001, we have a collaboration with Regeneron which grants us access to certain proprietary antigen binding domains covered by Regeneron's patent rights, including in particular the antigen binding domain incorporated into ADI-001. Additionally, there are multiple granted patents and pending patent applications in the U.S. and internationally directed to our TCRL platform technology, with actual and, in the case of pending applications, anticipated expiration dates between 2021 and 2037. Although certain earlier patents relating to our TCRL platform technology will expire in 2021, other patents covering this technology remain in force, or are expected to issue from pending applications, including three pending patent families directed to certain carcinoma, melanoma and glioblastoma targets, are expected to expire between 2036 and 2037. As a result, we do not expect that the expiration of the earlier patents in our TCRL portfolio, individually or in the aggregate, will have a material adverse effect on our future operations or financial position.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing of the first non-provisional application to which priority is claimed. In the U.S., patent term may be lengthened by patent term adjustment, which compensates a patentee

for administrative delays by the U.S. Patent and Trademark Office in granting a patent or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. In the U.S., the term of a patent that covers an FDA-approved drug may also be eligible for a patent term extension of up to five years under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term extension involves a complex calculation based on the length of time it takes for regulatory review. A patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, as well as novel discoveries, core technologies, and know-how, as well as our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights.

The patent positions of companies like us are generally uncertain and involve complex legal, scientific, and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by enforceable patents or will be commercially useful in protecting our commercial products and methods of using and manufacturing the same. We also cannot predict whether the patent applications it is currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold or control may be challenged, circumvented or invalidated by third parties. In addition, while we have confidence in our agreements and security measures, either may be breached, and we may not have adequate remedies. Further, our trade secrets may otherwise become known or independently discovered by competitors.

We have licensed various intellectual property and trade secrets to third parties for purposes of collaboration, product development and research and development.

Strategic Agreements

License and Collaboration Agreement with Regeneron

On July 29, 2016, we 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 our Series B preferred stock private placement transaction in July 2019 (as amended, referred to as the Regeneron Agreement).

Agreement Structure. The Regeneron Agreement has two principal components: (a) a research collaboration component under which the parties will research, develop, and commercialize next-generation engineered gamma delta immune cell therapeutics (ICPs) namely engineered gamma delta immune cells with CARs and TCRs directed to disease-specific cell surface antigens, which includes the grant of certain licenses to intellectual property between the two parties, and (b) for a certain period following the effective date, a license to us to use certain of Regeneron's proprietary mice to develop and commercialize ICPs generated by us, with certain limitations relating to targets under the Regeneron Agreement.

Research Collaboration. Research activities under the collaboration are governed by research plans, which include the strategy, goals, activities, and responsibilities of the parties with respect to a target. We are primarily responsible for generating, validating, and optimizing ICPs, developing processes for manufacture of ICPs, and certain preclinical and clinical manufacturing activities for ICP's; Regeneron's key responsibility is generating, validating, and optimizing CARs and TCRs that bind to the applicable target. The parties have formed a joint research committee to monitor and govern the research and development efforts during the research program term.

Rights to Research Targets. Under the terms of the five-year research collaboration, the parties will conduct research on mutually agreed upon targets. Regeneron may obtain exclusive rights for the targets that it chooses in accordance with the target selection mechanism set forth in the Regeneron Agreement, and we similarly may obtain exclusive rights for targets it chooses in accordance with such target selection mechanism. We have the right to develop and commercialize ICPs to the first collaboration target to come out of the research program. In connection with an IND submission, Regeneron has an option to exercise exclusive rights for ADI-002 and potentially for additional targets to be mutually agreed upon. For those targets it does not have an option to license, Regeneron has a right of first negotiation for up to two targets. Regeneron has the right to terminate the research program in its entirety (a) for convenience on six months prior written notice given at any time after December 31, 2019, or (b) following a change of control (as defined in the Regeneron Agreement) of us. The parties mutually agreed to their first product declaration criteria for collaboration ICP, CD20, in 2018.

Rights to Adicet-Developed Targets. Regeneron has an exclusive license to use targeting moieties generated by us by its use of Regeneron's proprietary mice to develop and commercialize non-ICPs.

Exclusivity. During the five-year target selection period, we may not directly or indirectly research, develop, manufacture or commercialize an ICP, or grant a license to do the foregoing, except pursuant to the Regeneron Agreement. For so long as either party is researching or developing an ICP to a target under the research program, neither party may research, develop, manufacture or commercialize any other ICP to such target, or grant a license to do the foregoing. And for so long as a party is researching, developing or commercializing an ICP to target that is licensed to it (and royalty bearing) under the agreement, neither party may research, develop, manufacture or commercialize any other ICP to such target, or grant a license to permit another party to do the foregoing. These exclusivity obligations are limited to engineered gamma delta immune cells to targets reasonably considered to have therapeutic relevance in oncology. The Regeneron Agreement includes certain exceptions to the exclusivity obligations of the parties, including with respect to targets that are rejected by one party in the target selection process, as well as protections in the event of a change of control of a party where the acquirer has a competing program.

Co-Funding and Profit Sharing. We have an option to co-fund specified portions of the future development costs for, and to co-promote, ICPs to a target for which Regeneron has exercised an option, and to participate in the profits for such target. We have the right to exercise this right in various geographic regions, including on a worldwide basis. In the event we exercise such right, the parties will share further development costs and revenues proportionally to their co-funding percentages.

Financial Terms. We received a non-refundable upfront payment of \$25.0 million from Regeneron upon execution of the Regeneron Agreement, received an aggregate of \$20.0 million of additional payments for research funding from Regeneron as of December 31, 2020. 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, 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 targeting moiety generated by us through the use of Regeneron's proprietary mice. We 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 we have exercised exclusive rights, and low to mid-single digit of 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 twelve (12) years from first commercial sale.

Other Terms. The Regeneron Agreement contains customary representations, warranties and covenants by us and Regeneron and includes (i) an obligation of ours to use commercially reasonable efforts to develop and commercialize at least one product based on a collaboration ICP that is not an optioned collaboration ICP for each collaboration target and (ii) an obligation of Regeneron to use commercially reasonable efforts to develop and commercialize at least one product based on an optioned collaboration ICP for each collaboration target. We and Regeneron are required to indemnify the other party against all losses and expenses related to breaches of the representations, warranties and covenants under the Regeneron Agreement.

Term and Termination. The term of the Regeneron Agreement expires, on a product-by-product basis, on the expiration of the obligation to pay royalties for such product. The Regeneron Agreement is subject to early termination by either party upon uncured material breach by the other party. The licenses to develop and commercialize an ICP to a target that one party has exclusively licensed may be terminated by such party for convenience.

Equity Investments. In connection with the collaboration, Regeneron and we entered into a side letter pursuant to which, among other matters, Regeneron was granted certain stockholder rights and investment rights in connection with our next equity financing that met certain criteria and in connection with an initial public offering by us. Regeneron exercised its investment right and purchased approximately \$10.0 million of our Series B preferred stock in a private placement transaction in July 2019.

License Agreement with TRDF

We and our wholly owned subsidiary, Adicet Bio Israel, Ltd. (formerly Applied Immune Technology Ltd.), are parties to an Amended and Restated License Agreement dated May 21, 2014, as was amended in June 2015 and January 2016, with Technion Research and Development Foundation Ltd. (TRDF) the technology transfer subsidiary of Technion – Israel Institute of Technology (Technion). The license agreement provides us with an exclusive, royalty-bearing, worldwide license, with a right to grant sublicenses, to make use of certain TRDF patents and know-how relating to moieties that recognize and bind to TCRLs, along with certain improvements and research results developed at TRDF and relating to either the licensed patents and know-how of TCRL, in each case for the purposes of research, development, and commercialization of specified products. We further obtained joint ownership rights in improvements, developments, and inventions developed in the laboratory of a specified professor under certain conditions, including where we provided specified amounts of funding for research specific to TCRL compounds. TRDF also grants us an exclusive, worldwide, assignable, sublicensable license to TRDF's rights in such jointly owned improvements, developments, and inventions. Technion further agrees not to enforce against us any TCRL-related technology owned by Technion but not licensed to us under the agreement, and to require its licensees to agree to the same. We are required to meet certain diligence obligations to preserve our exclusive licenses. Either Adicet or Technion may terminate the agreement or a specific license if the other party materially breaches its obligations under the agreement or with respect to a specific license granted under it and fails to cure that breach. We have the right to terminate the agreement at any time by providing notice to TRDF.

In return for the license, We are required to pay TRDF, for ten (10) years after the first commercial sale of a product for which it owes royalties under the agreement, on a licensed-product-by-licensed-product basis, (i) certain royalties in the low single-digit percentages of all net sales by us and any of our controlled affiliates, and (ii) the lesser of (a) a low single-digit percentage of net sales of our sublicensees, or (b) low double-digit percentage of amounts received by us or our controlled affiliates in the form of royalties on net sales from our sublicensees, subject to certain reductions. Furthermore, we agreed to pay for all patent filing and maintenance expenses for the patents included in the licenses granted to us by TRDF, with limited exceptions.

Under the agreement, TRDF reserves the right, for itself, alone or with other certain academic institutions, to utilize the licensed technology solely for educational and non-commercial research purposes.

The license agreement continues in full force and effect on a product-by-product and country-by-country basis until the expiration of all payment obligations for any licensed product as described above. Upon the expiration, we will have a fully paid-up, worldwide, non-exclusive license (with the right to grant sublicensees) to develop, have developed, manufacture, have manufactured, use, market, offer for sale, sell, have sold, import, export, and otherwise transfer physical possession or title to products for which royalties would have otherwise been due under the agreement.

Manufacturing

We are developing and enabling scalable and propriety cGMP-compliant manufacturing processes. We have invested resources to optimize our manufacturing process and plans to continue to invest to continuously improve our production and supply chain capabilities over time.

We manufacture cell-based immunotherapy products based on gamma delta T cells that are obtained from the blood of healthy donors who are unrelated to the patients that will be treated. These products are classed as allogeneic cell therapy products. Donor-derived blood is fractionated and the fractions containing gamma delta T cells are frozen prior to use in future manufacturing campaigns. We believe that our freezing and storing of the donor blood products allows us to efficiently schedule subsequent manufacturing steps. After obtaining blood products from healthy donors the manufacturing process begins with the activation of a subpopulation of gamma delta T cells using an antibody that is proprietary to us. This antibody, in combination with other factors including the cytokine, IL-2, induces gamma delta T cells to proliferate, whereupon we expose the cells to a viral vector that transfers a gene sequence encoding a CAR, or other gene sequences, to the proliferating cells. This step is referred to as the transduction step. Following the transduction step gamma delta T cells are induced to proliferate further with IL-2 before an enrichment step that increases the proportion of gamma delta T cells, removes unwanted residual alpha beta T cells and results in the CAR-modified gamma delta T cells drug product. CAR-modified gamma delta T cell products are then frozen in single-use vials for long-term storage at cryogenic temperatures. These storage conditions are designed to ensure stability of the cell-based drug products for protracted periods of time. The storage in single use vials is designed to simplify the handling and treatment administration. Just prior to administration of treatment, the vials will be thawed and then the contents infused into the patient. We believe that the single manufacturing process we are developing will be able to be completed in approximately two weeks and will result in sufficient quantities of drug product to treat numerous patients.

To date, we currently rely, and expects to continue to rely, on third parties for the manufacture of our product candidates and any products that we may develop. We have chosen to partner with a number of contract manufacturing organizations in the U.S. and Europe to access specific capabilities to ensure that the manufacturing process is highly scalable, closed and fully cGMP compliant. This strategy allows us to maintain a more flexible infrastructure while focusing our expertise on developing our products. In addition to the quality management systems utilized by strategic manufacturing partners, we have established a quality control and quality assurance program, which includes a set of standard operating procedures and specifications designed to ensure that our products are manufactured in accordance with cGMPs, and other applicable domestic and foreign regulations.

For example, we currently engage a single US-based third-party manufacturer to provide the active pharmaceutical ingredient for ADI-001. We also utilize separate third party contractors to manufacture cGMP-compliant starting and critical materials that are used for the manufacturing of our product candidates, such as donor blood products, gamma delta T cell activating antibody and viral vectors that are used to deliver the applicable CAR gene into the T cells. We believe all materials and components utilized in the production of the cell line, viral vector and final gamma delta T cell product are available from qualified suppliers and suitable for pivotal process development in readiness for registration and commercialization. Going forward, we intend to continue to expand our manufacturing capability through agreements with leading cell therapy contract manufacturing organizations.

If any of our current manufacturers becomes unavailable to us for any reason, we believe that there are a number of potential replacements, although we would likely incur some delay in identifying and qualifying such replacements. We plan to continue to create a robust supply chain with redundant sources of supply comprised of both internal and external infrastructure.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, including existing and novel therapies developed by biopharmaceutical companies, academic research institutions, governmental agencies and public and private research institutions, in addition to standard of care treatments.

Novartis and Kite Pharma (now Gilead) were the first to achieve FDA approval for autologous T cell therapies. In August 2017, Novartis obtained FDA approval to commercialize Kymriah®, for the treatment of children and young adults with B-cell ALL that is refractory or has relapsed at least twice. In May 2018, Kymriah® received FDA approval for adults with R/R large B-cell lymphoma. In October 2017, Kite Pharma obtained FDA approval to commercialize Yescarta®, the first CAR T cell product candidate for the treatment of adult patients with R/R large B-cell lymphoma. In July 2020, Gilead obtained FDA approval to commercialize Tecartus™, the first CAR T cell product candidate for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). In February 2021, Bristol Myers Squibb obtained FDA approval to commercialize Breyanzi® for the treatment of adults with R/R large B-cell lymphoma.

Due to the promising therapeutic effect of T cell therapies in clinical trials, we anticipate increasing competition from existing and new companies developing these therapies, as well as in the development of allogeneic T cell therapies generally. Potential T cell therapy competitors include, but are not limited to:

- *Allogeneic T cell therapy competition:* Atara Biotherapeutics, Inc., Allogene Therapeutics, Inc., Cellectis, S.A., Celyad S.A., CRISPR Therapeutics AG, Editas Medicine, Inc., Fate Therapeutics Inc., Gilead Sciences, Inc. (acquired Kite Pharma), Intellia Therapeutics, Inc., Poseida Therapeutics, Inc., Precision Biosciences, Inc., Immatix Biotechnologies GmbH, GammaDelta Therapeutics Limited, TC BioPharm Limited, Incysus Therapeutics, Inc. and Gadeta BV.
- *Autologous T cell therapy competition:* Adaptimmune Therapeutics PLC, Autolus Therapeutics plc, bluebird bio, Inc., Bristol-Myers Squibb Company, Gilead Sciences, Inc., Johnson & Johnson, Iovance Biotherapeutics, Inc., Mustang Bio, Inc., Novartis International AG, TCR² Therapeutics Inc. and Tmunity Therapeutics, Inc.

Although we believe our development of proprietary processes for engineering and manufacturing gamma delta T cells expressing CARs is unique due to what we believe is the enormous potential of these cells, it is likely that additional competition may arise from existing companies currently focusing on development of alpha beta or gamma delta T-cell therapies, or from new entrants in the field.

Competition may also arise from non-cell based immune oncology platforms. For instance, we may experience competition from companies, such as Amgen Inc., Bristol-Myers Squibb Company, F. Hoffmann-La Roche AG, Genmab A/S, GlaxoSmithKline plc, MacroGenics, Inc., Merus N.V., Regeneron Pharmaceuticals, Inc., and Xencor Inc., that are pursuing bispecific antibodies, which target both the cancer antigen and T-cell receptor, thus bringing both cancer cells and T cells in close proximity to maximize the likelihood of an immune response to the cancer cells. Additionally, companies, such as Amgen Inc., AbbVie, Daiichi Sankyo Company, Limited, GlaxoSmithKline plc, ImmunoGen, Inc., Immunomedics, Inc., and Seattle Genetics, Inc., are pursuing antibody drug conjugates, which utilize the targeting ability of antibodies to deliver cell-killing agents directly to cancer cells.

Many of our competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, preclinical testing, clinical trials, manufacturing, and marketing than we do. Future collaborations and mergers and acquisitions may result in further resource concentration among a smaller number of competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our own products, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and tolerability profile, convenience, price, reimbursement and cost of manufacturing.

These competitors may also vie for a similar pool of qualified scientific and management talent, sites and patient populations for clinical trials, and investor capital, as well as for technologies complementary to, or necessary for, our programs.

Government Regulation and Product Approval

As a biopharmaceutical company that operates in the U.S., we are subject to extensive regulation. Our cell products will be regulated as biologics. With this classification, commercial production of our products will need to occur in registered facilities in compliance with cGMP for biologics. The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a Biologics License Application (BLA) to the FDA for marketing authorization. Our products are considered more than minimally manipulated and will require evaluation in clinical trials and the submission and approval of a BLA before we can market them. Generally, before a new drug or biologic can be marketed, considerable data demonstrating our 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.

Government authorities in the U.S. (at the federal, state, and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the U.S. and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way but country-specific regulation remains essential in many respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

In the U.S., the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act (the FDCA), the Public Health Service Act (the PHSA), and their implemented regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a biological product may be marketed in the U.S. generally involves the following:

- completion of nonclinical laboratory tests and key animal studies according to good laboratory practices (GLPs), and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND application, which is subject to a waiting period of thirty (30) calendar days, must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board (IRB) or ethics committee for each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices (GCPs) and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed biological product for our intended use;
- submission to the FDA of a BLA for marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices (GTPs) for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval, or licensure, of the BLA prior to any commercial marketing or sale of the biologic in the U.S.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the key preclinical tests must comply with federal regulations and requirements including GLPs. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective thirty (30) days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and requests additional information and or places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to patients under the supervision of qualified investigators at independent clinical sites/hospitals, physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research patients provide informed consent. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. A clinical trial outside the U.S. may also be conducted under the authorization of similar regulatory authorities of the country/region. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product is typically introduced into healthy human subjects and tested for safety. However, in the case of some products for severe or life-threatening diseases, such as cancer or hematological malignancies that we aspire to treat, initial human testing is routinely conducted directly in ill patients with the approval of relevant ethics committee(s) under the supervision of a licensed physician.
- Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. In case of an accelerated BLA approval based on limited clinical data, FDA may mandate a Phase 4 clinical trial prior to full approval. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress

reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within fifteen (15) calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven (7) calendar days after the sponsor's initial receipt of the information.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may 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. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product according to the requirements of the phase of clinical development. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

Further, as a result of the COVID-19 pandemic, the extent and length of which is uncertain, we will be required to develop and implement additional clinical study policies and procedures designed to help protect study participants from the COVID-19 virus, which may include using telemedicine visits and remote monitoring of patients and clinical sites. We will also need to ensure data from our clinical studies that may be disrupted as a result of the pandemic is collected pursuant to the study protocol and is consistent with GCPs, with any material protocol deviation reviewed and approved by the site IRB. Patients who may miss scheduled appointments, any interruption in study drug supply, or other consequence that may result in incomplete data being generated during a study as a result of the pandemic must be adequately documented and justified. For example, on March 18, 2020, the FDA issued a guidance on conducting clinical trials during the pandemic, which describe a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical study report (or as a separate document) contingency measures implemented to manage the study, and any disruption of the study as a result of COVID-19; a list of all study participants affected by COVID-19-related study disruption by unique subject identifier and by investigational site, and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the study. As of August 4, 2020, the FDA continues to update and revise its guidance for ongoing clinical trials.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA submission must include results of product safety, efficacy, development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance or guarantee that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act (PDUFA), as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 or 74 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months from the filing date to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original

BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy (REMS) is necessary to assure the safe use of the biological product. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required. Both Kymriah® and Yescarta® were approved with a REMS.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. For cellular immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the cGTP, to the extent applicable. These are FDA regulations and guidance documents that in part govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissue, and cellular and tissue-based products (HCT/Ps) which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Pediatric Information

In addition, under the Pediatric Research Equity Act (PREA), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan (PSP), within sixty (60) days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric

studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug or biologic for this type of disease or condition will be recovered from sales in the U.S. for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval 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 full BLA, to market the same biologic 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. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a fast track product, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Regenerative Medicine Advanced Therapy (RMAT), designation was established by the FDA in 2017 to facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has 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. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Breakthrough therapy designation is also intended to expedite the development and review of products that treat serious or life-threatening conditions. The designation by FDA requires preliminary clinical evidence that a product candidate, alone or in combination with other drugs and biologics, demonstrates substantial improvement over currently available therapy on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

Fast Track designation, priority review, RMAT and breakthrough therapy designation do not change the standards for approval but may expedite the development or regulatory approval process for our products.

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, 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. Although a physician may prescribe a legally available product for an off-label use, if the physician deems such product to be appropriate in his/her professional medical judgment, a manufacturer may not market or promote off-label uses. However, it is permissible to share in certain circumstances truthful and not misleading information that is consistent with the product's approved labeling.

Further, additional FDA limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and may also require the implementation of other risk management measures, including a REMS, or the conduct of post-marketing studies to assess a newly discovered safety issue.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the adequate stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

We rely, and expect to continue to rely, on third parties to produce clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling.

including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

U.S. Marketing Exclusivity

The Biologics Price Competition and Innovation Act of 2009 (BPCIA), amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its molecule as highly similar to an approved innovator biologic, among other requirements. The BPCIA, however, bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval. This 12-year period of data exclusivity may be extended by six months, for a total of 12.5 years, if the FDA requests that the innovator company conduct pediatric clinical investigations of the product.

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Pediatric exclusivity is another type of regulatory market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services (CMS), other divisions of the U.S. Department of Health and Human Services (HHS) (e.g., the Office of Inspector General, the U.S. Department of Justice (DOJ), and individual U.S. Attorney offices within the DOJ, and state and local governments). For example, our business practices, including any of our research and future sales, marketing and scientific/educational grant programs may be required to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the patient data privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), transparency requirements, and similar state, local and foreign laws, each as amended.

The federal Anti-Kickback Statute 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 purchasing, leasing, ordering or arranging for the purchase, lease or order of any item, good, facility or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and other individuals and entities on the other. 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 and require strict compliance in order to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of the facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Rather, if "one purpose" of the

remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. In addition, the Affordable Care Act codified case law that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to, among others, a federal healthcare program that the person knows or should know is for a medical or other item or service that was not provided as claimed or is false or fraudulent.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. For example, pharmaceutical and other healthcare companies have been, and continue to be, investigated or prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor. These laws are enforced by various state agencies and through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant federal government compliance guidance, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures. In addition, certain state and local laws require the registration of pharmaceutical sales representatives.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their implementing regulations, impose requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to business associates that are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) annually report information to CMS related to certain payments or other transfers of value made or distributed to physicians, as defined by such law, and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, 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 the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the U.S. and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the U.S., third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. 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.

Different pricing and reimbursement schemes exist in other countries. In the European Union (EU), governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, 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 the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the U.S. has increased and we expect will continue to increase the pressure on healthcare pricing. 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.

Healthcare Reform

In the U.S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- created an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;

- increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price (AMP);
- created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 50% (increase to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and added new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expanded the entities eligible for discounts under the 340B Drug Discount Program;
- created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expanded healthcare fraud and abuse laws, including the Anti-Kickback Statute and the Foreign Corrupt Practices Act (FCPA), created new government investigative powers, and enhanced penalties for noncompliance;
- created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- required reporting of certain financial arrangements with physicians and teaching hospitals;
- required annual reporting of certain information regarding drug samples that manufacturers and distributors provide to physicians;
- established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and
- created a licensure framework for follow on biologic products.

There remain legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, the former U.S. President signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance, commonly known as the "individual mandate", as part of the Tax Cuts and Jobs Act of 2017 (Tax Act). On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit held that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and held oral arguments on November 10, 2020. It is unclear how these developments, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act.

In addition, 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 (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 March 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. The Middle Class Tax Relief and Job Creation Act of 2012 required that CMS reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting. 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.

Additionally, 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, 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.

At the federal level, the former U.S. Presidential administration's budget proposal for the fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. HHS has solicited feedback on some of the measures supported by the prior administration and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. It is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021.

Additionally, the FDA released a final rule 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. 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 will be 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. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021 and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 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 an order entered by the U.S. District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2023. Further, implementation of this change 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.

Individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Individual states in the U.S. have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We anticipate that these and other healthcare reform efforts will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could materially harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. 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.

The Foreign Corrupt Practices Act

The FCPA prohibits any U.S. individual or business from offering, paying, promising to pay, or authorizing payment of money or anything of value, to any person, while knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to any foreign official, political party or candidate to influence the foreign official in his or her official capacity, induce the foreign official to do or omit to do an act in violation of his or her lawful duty, or to secure any improper advantage in order to assist the individual or business in obtaining or retaining business.

The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are owned and operated by the government, and doctors and other hospital employees are considered foreign officials for the purposes of the statute. Certain payments made in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products.

Accordingly, if we expand our presence outside of the U.S., we will need to dedicate additional resources to complying with the laws and regulations in each jurisdiction in which it plans to operate. Therefore, this may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

Packaging and Distribution in the U.S.

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations.

Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. We maintain workers' compensation insurance to cover costs and expenses it may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against it. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Europe / Rest of World Government Regulation

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the U.S. have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit an MAA. The application used to file the BLA in the U.S. is similar to that required in the EU, with the exception of, among other things, country-specific document requirements.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

European Union General Data Protection Regulation

In addition to EU regulations related to the approval and commercialization of our products, we may be subject to the EU's General Data Protection Regulation (GDPR). The GDPR imposes stringent requirements for controllers and processors of personal data of persons in the EU, 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 contracts 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 we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules.

California recently enacted legislation, effective January 1, 2020, that has been dubbed the first “GDPR-like” law in the U.S. Known as the California Consumer Privacy Act (CCPA), it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, provides such consumers new ways to opt-out of certain sales of personal information, and allows for a new cause of action for data breaches. As our business progresses, the CCPA may impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Corporate Information

Prior to September 15, 2020, we were a clinical-stage biopharmaceutical company known as resTORbio, Inc. 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 lifespan. 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, Inc. merged with and into Adicet Bio, Inc., with Adicet Bio, Inc. surviving as a wholly-owned subsidiary of resTORbio and changing our name to Adicet Therapeutics, Inc. 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. At the Effective Time of the Merger, each outstanding share of former our capital stock was converted into the right to receive 0.1240 shares of resTORbio common stock.

Our website is located at www.adicetbio.com. Our common stock trades on the Nasdaq Global Market under the symbol “ACET.”

Employees

As of March 10, 2021, we had 81 full-time employees, one part-time employee, and 20 consultants. 51% of our employees are female; 23 of our employees hold a Ph.D; 4 of our employees hold a M.D. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

In addition to providing attractive and competitive total rewards packages to employees, Adicet believes in fostering individual and organizational effectiveness by offering our employees professional development opportunities that are designed to provide individuals and the organization with the knowledge and skills to respond effectively to current and future business demands and to provide ongoing support to the organization’s development efforts. Our culture is one that actively supports the application of new knowledge and skills on the job. We plan to continue to evolve and add to our suite of human capital resources as we grow.

Available Information

Our Internet address is www.adicetbio.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act), are available through the “Investors” portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, our filings with the SEC may be accessed through the SEC’s Interactive Data Electronic Applications system at <http://www.sec.gov>. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. In evaluating the Company and our business, you should carefully consider the following risks and uncertainties, together with all other information in this Annual Report on Form 10-K, including our consolidated financial statements and related notes and “Management’s Discussion and Analysis of Results of Operations and Financial Condition,” as well as our other filings with the Securities and Exchange Commission, before investing in our common stock. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations. The market price of our common stock could decline if one or more of these risks or uncertainties actually occur, causing you to lose all or part of your investment in our common stock. The risks and uncertainties we describe below are not the only ones we face. Additional risks and uncertainties that we currently do not know about or that we currently believe to be immaterial may also impair our business. Certain statements below are forward-looking statements. See “Special Note Regarding Forward-Looking Statements and Industry Data” in this Annual Report on Form 10-K.

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 you 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 years ended December 31, 2020, 2019 and 2018, we reported net losses of \$36.8 million, 28.1 million and \$9.3 million, respectively. As of December 31, 2020, we had an accumulated deficit of \$106.5 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 Annual Report on Form 10-K 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 intend to initiate the first-in-human clinical trial to assess safety and efficacy of ADI-001 in NHL patients in the first quarter of 2021. ADI-002 is also in the early stage of development and we intend to file an IND in late 2021.

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 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.

Interim "top line" and preliminary data from our clinical trials that we may announce or publish from time to time 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.

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

Preliminary or “top line” data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously 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.

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 and, subject to the FDA’s regulatory process for review of INDs, initiate Phase 1 clinical trials of ADI-002 in late 2021. 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 GCP requirements or applicable regulatory guidelines in other countries;

- transfer of manufacturing processes to any new 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

We do not currently operate our own manufacturing facility, which would require significant resources and any failure to successfully manufacture our products could adversely affect our clinical trials and the commercial viability of our product candidates.

We may not be able to achieve clinical or commercial manufacturing and cell processing on our own or through our CMOs, including mass-producing off-the-shelf product to satisfy demands 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 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.

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 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, cash equivalents and marketable debt securities 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; On December 2, 2020, the Office of Inspector General, or OIG, published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. This rule (with exceptions) became effective January 19, 2021. Implementation of this change 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 continue to evaluate what effect, if any, the rule will have on our business;
- 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 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 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’ 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, or the 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, or 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.

Risks Related to Our Financial Position

Our ability to use net operating losses and research and development credits 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, which we entered into on April 28, 2020 (the Loan Agreement) at an interest rate equal to the greater of 0.25% above the Prime Rate or 5.00%. 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 Annual Report on Form 10-K, 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 years ended December 31, 2020, 2019 and 2018, 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 our 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 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.

As a result, our ability to advance any gamma delta immune cell therapeutics outside of the scope of the research plan agreed on with Regeneron is limited through July 29, 2021. We may have to forego business opportunities and will also be limited in the gamma delta immune cell therapeutics we can advance on our own. The restrictions on internal development may also prevent us from, outside of the scope of research conducted with Regeneron, improving our own technologies relating to gamma delta immune cells. These limitations 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, 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 may rely on third parties to manufacture our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if approved.

We must currently rely on outside vendors to manufacture supplies and process our product candidates. We have 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 and 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 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. In addition, 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. In addition, 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. Further, 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 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 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. 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.

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 payers rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payers and reduce the willingness of physicians to use our product candidates.

In the 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 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 Affordable Care Act. Since January 2017, the former U.S. President signed several Executive Orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance, commonly known as the "individual mandate", as part of the Tax Cuts and Jobs Act of 2017 (Tax Act). On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit held that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and held oral arguments on November 10, 2020. It is unclear how these developments, future decisions, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

In addition, 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 March 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the 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 the federal level, the former U.S. Presidential administration's budget proposal for the fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. HHS has solicited feedback on some of the measures supported by the prior administration and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. It is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021. Individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Additionally, the FDA released a final rule 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. 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 will be 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. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 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 an order entered by the U.S. District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2023. Further, implementation of this change 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.

Risks Related to Our Intellectual Property

Risks Related to Third Party Intellectual Property.

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

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

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

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

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

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

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

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Trade secrets, however, may be difficult to protect. Although we require all of our employees to assign their inventions to us, and 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 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We have offices in Boston, Massachusetts, and Menlo Park, California. Our principal executive offices are located at 500 Boylston Street, 13th Floor, Boston, MA 02116. This lease expires on July 31, 2026. We are permitted to assign, sublease or transfer this lease, with the consent of the landlord, which consent shall not be unreasonably withheld. We believe that this office is sufficient to meet our current needs and that suitable additional space will be available as and when needed. We also leased office and laboratory space located in Menlo Park, California. The lease expires on March 31, 2022. In addition, in October 2018, we entered a new lease for office and laboratory space in Redwood City, California. We expect to complete occupancy in the new facility in second quarter of 2022.

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock trades on The Nasdaq Global Market under the symbol “ACET”. Trading of our common stock commenced on January 26, 2018, in connection with our initial public offering of resTORbio. Prior to that time, there was no established public trading market for our common stock.

As of March 10, 2021, we had approximately 45 holders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and growth of our business. We do not expect to pay any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, then applicable contractual restrictions and any other factors deemed relevant by our board of directors. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Equity Compensation Plan

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

Securities Purchase Agreement

On February 12, 2021, we entered into a stock purchase agreement with certain existing investors for \$15.0 million of shares of our common stock, with an initial closing for certain investors held simultaneously with the closing of our February 2021 public offering and a subsequent closing for certain additional investors. Pursuant to the terms of the private placement, we issued 1,153,840 shares of common stock at a price of \$13.00 per share, which was the price per share of our February 2021 public offering. We received the full proceeds from the sale and did not pay any underwriting discounts or commissions with respect to the shares of common stock that sold in the concurrent private placement. Proceeds from the private placement will be used primarily to fund activities related to our internal discovery research, other pipeline candidates and to fund the continued development of our gamma delta T cell platform; the external costs for the development of ADI-001 through the completion of a Phase 1 dose expansion study for ADI-001 in NHL; the external costs for the development of ADI-002 through the completion of a Phase 1 dose finding study for ADI-002 in solid tumors; and the remainder, if any, to fund working capital and other general corporate purposes. The private placement was exempt from registration pursuant to Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering.

Purchase of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. Reserved.

Item 7. 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 Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K 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 Annual Report on Form 10-K.

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. We believe our approach has potentially significant advantages over alpha beta T cells, which are the basis of standard CAR-T cell therapies. We are developing proprietary processes for engineering and manufacturing product candidates based on gamma delta T cells from the blood of healthy donors, resulting in high yields of cells with efficacious tumor-killing activity in preclinical studies. 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 produced 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. Due to certain unique properties of gamma delta T cells, we believe that our product candidates can be developed to have an inherent capacity to recognize and kill circulating tumor cells and to infiltrate and kill 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). The active IND enables us to initiate the first-in-human clinical trial to assess safety and efficacy of ADI-001 in NHL patients in March 2021. 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 finding portion followed by dose expansion cohorts to explore the activity of ADI-001 in multiple subtypes of NHL. Site initiation activities are underway and interim clinical data from this study are expected in 2021. We intend to file an IND with the FDA in late 2021 for ADI-002, our first solid tumor product candidate.

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

In February 2021, we completed an underwritten public offering of 10,575,513 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to an additional 1,344,743 shares of common stock at a public offering price of \$13.00 per share. The 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. We received the full proceeds from the sale and did not pay any underwriting discounts or commissions with respect to the shares of common stock that sold in the concurrent private placement. The shares sold in the private placement were not registered under the Securities Act.

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. Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses.

As local jurisdictions continue to put restrictions in place, our ability to continue to operate our business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. In response to the COVID-19 pandemic, we tasked members of our Executive Leadership team, Human Resources, Facilities and Operations and Employee Communications to develop guidelines and processes intended to raise awareness of new health and well-being protocols and potentially helpful practices for cross-functional teamwork for our employees.

These efforts have included implementation of remote working and shift scheduling, providing our team members practical recommendations based on guidelines from the Centers for Disease Control and Prevention, State of California Department of Health Care Services, State of Massachusetts Department of Public Health, OSHA and other regional government entities. In addition, we are committed to updating these recommendations and communicating new pertinent information when available. While doing so we are sensitive to ensuring any guidance provided may vary by locality based on government orders and regulations.

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

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

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 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 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 Annual Report on Form 10-K, we were in compliance with such covenants and had no indebtedness outstanding under the Loan Agreement.

At-the-Market (ATM) Offering

On December 1, 2020, we entered into a Sales Agreement (the 2020 Sales Agreement) with Evercore Group L.L.C. and H.C. Wainwright & Co., LLC (collectively, the Agents), pursuant to which we could sell, from time to time, at our option, up to an aggregate of \$50.0 million of shares of our common stock, through the Agents, as our sales agents. No shares were sold under the 2020 Sales Agreement before it was terminated in February 2021.

Financial Operations Overview

Revenue

We have no products approved for commercial sale and do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for our product candidates, which we expect will not be for at least several years, if ever. Our revenues to date are generated from our License and Collaboration Agreement with Regeneron Pharmaceuticals, Inc. (Regeneron) and the agreement referred to as the “Regeneron Agreement”. The primary purpose of the Regeneron Agreement is to establish a strategic relationship to identify and validate appropriate targets and work together to develop a pipeline of engineered immune cell products (Collaboration ICPs) for the selected targets. The Regeneron Agreement provides for the following: (i) licenses to our technology, (ii) research and development services, (iii) services or obligations in connection with participation in the research committee, (iv) information sharing, and (v) manufacturing services to manufacture of Collaboration ICPs for the research programs. The Regeneron Agreement provides Regeneron an option to obtain an exclusive, royalty-bearing development and commercial license under our intellectual property to develop and commercialize the optioned Collaboration ICPs ready for an IND submission.

We received a non-refundable upfront payment of \$25.0 million from Regeneron upon execution of the Regeneron Agreement on July 29, 2016 and have received an aggregate of \$20.0 million of additional payments for research funding from Regeneron as of December 31, 2020. 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 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 anticipated expenses related to the Merger and future 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 Years Ended December 31, 2020 and 2019

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

	Year Ended December 31,		Change	% Change
	2020	2019		
Revenue – related party	\$ 17,903	\$ 995	\$ 16,908	1699%
Operating expenses				
Research and development	34,334	23,691	10,643	45%
General and administrative	22,760	8,692	14,068	162%
Total operating expenses	57,094	32,383	24,711	76%
Loss from operations	(39,191)	(31,388)	(7,803)	25%
Interest income	785	938	(153)	-16%
Interest expense	(134)	—	(134)	100%
Other income (expense), net	(953)	2,331	(3,284)	-141%
Loss before income tax benefit	(39,493)	(28,119)	(11,374)	40%
Income tax expense (benefit)	(2,815)	19	(2,834)	*%
Net loss	<u>\$ (36,678)</u>	<u>\$ (28,138)</u>	<u>\$ (8,540)</u>	<u>30%</u>

* Not meaningful

Revenue

Revenue increased by \$16.9 million, or 1699%, for the year ended December 31, 2020 compared to the year ended December 31, 2019 resulting from the increase in revenue recognized under the Regeneron Agreement. The increase in revenue recognized under the Regeneron Agreement for the year ended December 31, 2020 was primarily due to the following:

- In April 2019, we executed an amendment to the Regeneron Agreement, according to which the future research program fees that were due on the third and fourth anniversaries of the Regeneron Agreement were replaced with payments based on achievement of certain development and regulatory milestones. After the amendment became

effective in July 2019, these payments were accounted for as variable consideration and excluded from the transaction price due to substantial uncertainties related to achieving the milestones and, as a result, earning such payments. There was also a significant change in forecasted research and development expenses during the third quarter of 2019.

- In June 2020, we achieved a milestone under the Regeneron Agreement relating to the selection of a clinical candidate for ADI-002. This resulted in an increase in the transaction price of the Regeneron Agreement by \$10.0 million. As a result, we recognized an additional \$5.0 million in revenue during the three months ended June 30, 2020.
- The proportional performance under the Regeneron Agreement measured, using a cost-based input method, was higher during the year ended December 31, 2020 as compared to the year ended December 31, 2019 due to increased research and development activities.

Research and development

	Year Ended December 31,	
	2020	2019
Payroll and personnel expenses ⁽¹⁾	\$ 15,490	\$ 10,104
Costs incurred under agreements with consultants, CMOs, and CROs	11,195	5,982
Lab materials, supplies, and maintenance of equipment used for research and development activities	4,401	4,961
Other research and development expenses ⁽²⁾	3,248	2,644
Total research and development expenses	\$ 34,334	\$ 23,691

(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 \$10.6 million, or 46%, during the year ended December 31, 2020 compared to the year ended December 31, 2019. The increase in research and development expenses was primarily due to an increase of \$5.3 million in personnel expenses, including 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 \$0.9 million, a portion which was attributable to the modification of the outstanding in-the-money stock options and restricted stock units held by resTORbio employees, in connection with the Merger. In addition, there was an increase of \$5.4 million in fees incurred for CRO and CMO costs due to initiating and ramping up manufacturing and preclinical development activities related to our first product candidate, and an increase of \$0.6 million in allocated facility-related costs and other general support services. There was also a change in the fair value of our in-process research & development (IPR&D) asset and contingent consideration liability (CVR) of \$2.3 million and \$1.9 million respectively, which represented a net charge of \$0.4 million to research and development expenses. These increases were offset by a decrease in \$0.6 million in lab materials, supplies, and maintenance of equipment used for research and development activities and a decrease in consulting fees of \$0.2 million.

General and administrative

General and administrative expenses increased by \$14.1 million, or 162%, during the year ended December 31, 2020 as compared to the year ended December 31, 2019. The increase in general and administrative expenses was primarily due to an increase of \$7.1 million of professional fees for legal, consulting, accounting, tax and other services incurred in connection with the Merger, an increase of \$5.1 million of payroll and personnel expenses, which includes salaries, benefits, bonuses, and stock-based compensation expenses, and temporary contractor fees, and an increase of \$1.3 million in facilities and other expenses. The increase in payroll and personnel expenses includes payments of \$0.7 million to Dr. Singhal, the former Chief Executive Officer in accordance with the Transition Agreement executed with him, incremental stock compensation expense of \$0.7 million recognized resulting from the modification of Dr. Singhal's stock options in connection with the Merger, and stock compensation expense of \$1.0 million attributable to post combination services recognized resulting from the modification of the outstanding in-the-money stock options and restricted stock units held by resTORbio employees, in connection with the Merger.

Interest income

Interest income decreased by \$0.2 million, or 16%, during the year ended December 31, 2020 compared to the year ended December 31, 2019, which was primarily attributable to the decrease in average balance of cash and cash equivalents and marketable debt securities.

Interest Expense

Interest expense increased by \$0.1 million during the year ended December 31, 2020 as compared to the year ended December 31, 2019 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 \$3.3 million, or 141%, during the year ended December 31, 2020 compared to the year ended December 31, 2019. The decrease was primarily due to a decrease in the fair value of redeemable convertible preferred stock warrant liability of \$0.9 million in 2020 compared to an increase in the fair value of the redeemable convertible preferred stock tranche liability and the Technion Research and Development Foundation (TRDF) liability of \$2.0 million in 2019.

Income tax expense

We recognized an income tax benefit of \$2.8 million during the year ended December 31, 2020 compared to the income tax expense of \$19,000 for the year ended December 31, 2019. The income tax benefit during the year ended December 31, 2020 was a result of the recognition of a net operating loss carryback under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) which was enacted on March 27, 2020 in response to the COVID-19 pandemic. This generated a refund of income taxes paid by us during the year ended December 31, 2017. In accordance with Accounting Standards Codification (ASC) 740, Income Taxes, we recorded the effect of an enacted change in a tax law in the period that includes the enactment date.

Comparison of the Years Ended December 31, 2019 and 2018

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

	Year Ended December 31,		Change	% Change
	2019	2018		
Revenue – related party	\$ 995	\$ 8,181	\$ (7,186)	-88%
Operating expenses:				
Research and development	23,691	14,717	8,974	61%
General and administrative	8,692	8,428	264	3%
Total operating expenses	32,383	23,145	9,238	40%
Loss from operations	(31,388)	(14,964)	(16,424)	110%
Interest income	938	543	395	73%
Other income (expense), net	2,331	4,533	(2,202)	-49%
Loss before income tax provision (benefit)	(28,119)	(9,888)	(18,231)	184%
Income tax provision (benefit)	19	(589)	608	-103%
Net loss	\$ (28,138)	\$ (9,299)	\$ (18,839)	203%

Revenue

Revenue decreased by \$7.2 million, or 88%, for the year ended December 31, 2019 compared to the year ended December 31, 2018 resulting from the decrease in revenue recognized under the Regeneron Agreement.

The decrease in revenue recognized under the Regeneron Agreement during the year ended December 31, 2019 was primarily due to an amendment to the Regeneron Agreement. In April 2019, we executed an amendment to the Regeneron Agreement according to which future research program fees that were due on the third and fourth anniversaries of the Regeneron Agreement were replaced with the payments based on achievement of certain development and regulatory milestones. After the amendment became effective in July 2019, these payments were accounted for as variable consideration and excluded from the transaction price due to substantial uncertainties related to achieving the milestones and, as a result, earning with such payments. This resulted in a decrease in the cumulative revenue recognized under the Regeneron Agreement (see critical accounting policy on revenue recognition below).

Research and development

	Year Ended December 31,	
	2019	2018
Payroll and personnel expenses ⁽¹⁾	\$ 10,104	\$ 7,449
Costs incurred under agreements with consultants, CMOs, and CROs	5,982	1,054
Lab materials, supplies, and maintenance of equipment used for research and development activities	4,961	3,857
Other research and development expenses ⁽²⁾	2,644	2,357
Total research and development expenses	<u>\$ 23,691</u>	<u>\$ 14,717</u>

- (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 \$9.0 million, or 61%, for the year ended December 31, 2019 compared to the year ended December 31, 2018. The increase in research and development expenses was primarily due to an increase of \$4.9 million in fees paid to CMOs due to initiating and ramping up manufacturing and preclinical development activities related to our first product candidate, an increase of \$2.7 million in payroll and personnel expenses, including salaries, bonuses, benefits and stock-based compensation expenses due to increases in headcount of employees involved in research and development activities, an increase of \$1.1 million in laboratory materials, supplies, and maintenance of equipment used for research and development activities, and an increase of \$0.3 million in facility-related costs and other general support services.

General and administrative

General and administrative expenses increased by \$0.3 million, or 3%, for the year ended December 31, 2019 compared to the year ended December 31, 2018. The increase in general and administrative expenses was primarily due to an increase of \$0.7 million of professional fees for legal, consulting, accounting, tax and other services and an increase of \$0.4 million in depreciation, rent, travel and other expenses, offset by a decrease of \$0.8 million of payroll and personnel expenses, including salaries, bonuses, benefits and stock-based compensation expenses largely due to a decrease in stock-based compensation expenses resulting from accounting for forfeitures of unvested stock options of terminated employees during the year that was partly offset by increases in headcount at the senior management level.

Interest income

Interest income increased by \$0.4 million, or 73%, for the year ended December 31, 2019 compared to the year ended December 31, 2018, which was primarily attributable to interest income from an increase in cash and cash equivalents and marketable debt securities as a result of the proceeds received from the sale of shares of Series B redeemable convertible preferred stock in the third quarter of 2019.

Other income (expense), net

Other income (expense), net decreased by \$2.2 million, or 49%, for the year ended December 31, 2019 compared to the year ended December 31, 2018, which was primarily due to a decrease in fair value of redeemable convertible preferred stock tranche liability by \$2.5 million, partially offset by an increase in fair value of redeemable convertible preferred stock warrant liability of \$0.3 million.

Income tax expense (benefit)

During the year ended December 31, 2019, we recorded income tax expense of less than \$0.1 million. For the year ended December 31, 2018, we recorded an income tax benefit of \$0.6 million which was primarily due to the New York state net operating loss carryback, which generated a refund of income taxes paid for the year ended December 31, 2017.

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. As of December 31, 2020, we had cash,

cash equivalents and marketable debt securities of \$94.6 million. In February 2021, we completed an underwritten public offering of 10,575,513 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to an additional 1,344,743 shares of common stock at a public offering price of \$13.00 per share. The 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.

We expect that the cash, cash equivalents, and marketable debt securities 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.

Redeemable Convertible Preferred Stock

Series A Redeemable Convertible Preferred Stock

From 2015 to 2018, we issued 30,233,758 shares of our Series A redeemable convertible preferred stock at \$1.20 per share for total gross proceeds of \$36.3 million.

We also issued 411,892 and 67,656 shares of our Series A redeemable convertible preferred stock in connection with an amendment of the license agreement with the TRDF in February 2016 and February 2019, respectively.

In January 2016 and February 2016, we issued 629,633 shares of our Series A-1 redeemable convertible preferred stock and 2,428,688 shares of Series A-2 redeemable convertible preferred stock as part of the purchase consideration for Applied Immune Technologies, Ltd. (AIT), respectively.

Following the closing of the Merger, all Series A, Series A-1, and Series A-2 redeemable convertible preferred stock were converted in 4,980,151 shares of our common stock.

Series B Redeemable Convertible Preferred Stock

In 2019, we issued 57,004,415 share of Series B redeemable convertible preferred stock at \$1.4034 per share for gross proceeds of \$80.0 million.

In connection with Series B redeemable convertible preferred stock financing transactions, we issued to our financial advisor warrants to purchase 1,781,387 shares of our Series B redeemable convertible preferred stock at an exercise price of at \$1.4034 per share.

Following the closing of the Merger, all Series B redeemable convertible preferred stock were converted in 7,068,520 shares of our common stock.

Loan Agreement

On April 28, 2020, we entered into the Loan Agreement with Pacific Western Bank (the 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 the 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 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 December 31, 2020, 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.

At-the-Market (ATM) Offering

On December 1, 2020, we entered into a Sales Agreement (the 2020 Sales Agreement) with Evercore Group L.L.C. and H.C. Wainwright & Co., LLC (collectively, the Agents), pursuant to which we could sell, from time to time, at our option, up

to an aggregate of \$50.0 million of shares of our common stock, through the Agents, as our sales agents. No shares were sold under the 2020 Sales Agreement before it was terminated in February 2021.

Public Offering

In February 2021, we completed an underwritten public offering of 10,575,513 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to an additional 1,344,743 shares of common stock at a public offering price of \$13.00 per share. The 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.

Future Funding Requirements

We have incurred losses since inception and have incurred losses of \$36.8 million, \$28.1 million and \$9.3 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of \$106.5 million.

As of December 31, 2020, we had cash, cash equivalents and marketable debt securities of \$94.6 million. We believe that our cash, cash equivalents and marketable debt securities will be sufficient for us to continue as a going concern for at least 12 months from the issuance date of our consolidated financial statements as of and for the year ended December 31, 2020 included elsewhere in this Annual Report on Form 10-K. 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 Annual Report on Form 10-K 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):

	Year Ended December 31,		
	2020	2019	2018
Net cash provided by (used in):			
Operating activities	\$ (41,552)	\$ (27,882)	\$ (18,180)
Investing activities	115,217	(47,931)	(16,058)
Financing activities	303	76,945	11,046
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 73,968</u>	<u>\$ 1,132</u>	<u>\$ (23,192)</u>

Cash Flows from Operating Activities

Net cash used in operating activities was \$41.6 million for the year ended December 31, 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 \$36.7 million, adjusted for non-cash activities of \$8.6 million. The non-cash activities are composed of depreciation expense of \$1.2 million, a non-cash lease expense of \$0.7 million, stock-based compensation expense of \$5.3 million, a non-cash change in fair value of the redeemable convertible preferred stock warrant liability of \$0.9 million, a non-cash expense for impairment of IPR&D of \$2.3 million, a gain on the remeasurement of contingent consideration liability of \$1.9 million, and amortization of the deferred debt issuance cost of \$0.1 million. Changes in operating assets and liabilities were composed of an increase in prepaid expenses and other current assets of \$3.2 million, an increase in other non-current assets of \$1.3 million, a decrease in contract liabilities of \$7.9 million, a decrease in deferred tax liability of \$0.2 million, a decrease in lease liabilities of \$0.9 million, and a decrease in accounts payable of \$0.8 million, partially offset by an increase in accrued and other current liabilities of \$0.8 million. The increase in prepaid expenses and other current assets resulted from the prepayment for director and officer insurance after the close of the Merger, timing of payments to our CROs and CMOs and an increase in federal tax receivable. The decrease in contract liabilities is due to the recognition of revenue under the Regeneron Agreement. Decreases in accounts payable and increase in accrued and other liabilities resulted from the timing of payments to our service providers.

Net cash used in operating activities was \$27.9 million for the year ended December 31, 2019. 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 \$28.1 million, adjusted for a non-cash change in fair value of the redeemable convertible preferred stock tranche liability and

TRDF liability of \$2.0 million, a non-cash change in fair value of redeemable convertible preferred stock warrant liability of \$0.3 million, a decrease in contract liabilities of \$1.0 million, and a decrease in accrued and other current liabilities of \$0.4 million, partially offset by depreciation expense of \$1.2 million, stock-based compensation expense of \$1.2 million, a decrease in prepaid expenses and other current assets of \$1.4 million, and an increase in accounts payable of \$0.5 million. The decrease in prepaid expenses and other current assets, decrease in accrued and other current liabilities, and increase in accounts payable resulted from the timing of payments to our service providers.

Net cash used in operating activities was \$18.2 million for the year ended December 31, 2018. 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 \$9.3 million, adjusted for a non-cash change in fair value of redeemable convertible preferred stock tranche liability and TRDF liability of \$4.5 million, a decrease in contract liabilities of \$3.2 million, an increase in prepaid expenses and other current assets of \$2.8 million, a decrease in accrued and other current liabilities of \$1.3 million, a decrease in accounts payable of \$0.3 million, and an increase in other non-current assets of \$0.3 million, partially offset by non-cash depreciation expense of \$1.2 million and stock-based compensation expense of \$2.5 million. The increase in prepaid expenses and other current assets and decreases in accounts payable and accrued and other current liabilities resulted from the timing of payments to our service providers.

Cash Flows Used in Investing Activities

Net cash provided by investing activities was \$115.2 million for the year ended December 31, 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 \$57.8 million, partially offset by purchases of marketable debt securities of \$5.7 million and purchases of property and equipment of \$1.0 million.

Net cash used in investing activities was \$47.9 million for the year ended December 31, 2019, which related to purchases of marketable debt securities of \$76.1 million and purchases of property and equipment of \$1.1 million, partially offset by proceeds from maturities of marketable debt securities of \$29.1 million.

Net cash used in investing activities was \$16.1 million for the year ended December 31, 2018, which related to purchases of marketable debt securities of \$15.2 million and purchases of property and equipment of \$0.9 million.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$0.3 million for the year ended December 31, 2020, due to cash proceeds of \$0.5 million from exercise of stock options partly offset by payment of debt issuance costs of \$0.2 million.

Net cash provided by financing activities was \$76.9 million for the year ended December 31, 2019, primarily due to net proceeds from the sale of shares of Series B redeemable convertible preferred stock.

Net cash provided by financing activities was \$11.0 million for the year ended December 31, 2018, due to net proceeds from the sale of shares of Series A redeemable convertible preferred stock of \$10.8 million and cash proceeds of \$0.2 million from exercise of stock options.

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 premise in the same building with additional space. The initial annual base rent for this lease was \$0.6 million and increases 2% annually. 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 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.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our 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 CVR, 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.

Revenue Recognition

Under ASC 606, *Revenue from Contracts with Customers* (ASC 606), we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps as prescribed by ASC 606:

- (i) identify the contract(s) with a customer;
- (ii) identify the performance obligations in the contract;
- (iii) determine the transaction price;
- (iv) allocate the transaction price to the performance obligations in the contract; and
- (v) recognize revenue when (or as) the Company satisfies a performance obligation.

A contract with a customer exists when (i) we enter into a legally enforceable contract with a customer that defines each party's rights regarding the products or services to be transferred and identifies the payment terms related to these products or services, (ii) the contract has commercial substance and (iii) we determine that collection of substantially all consideration for products or services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

At contract inception, once the contract is determined to be within the scope of ASC 606, we identify the goods or services promised and determine the performance obligations by assessing whether each promised good or service is distinct. Goods or services that are not distinct are bundled with other goods or services in the contract until a bundle of goods or services that is distinct is created. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Our revenues are derived through the Regeneron Agreement. The terms of the Regeneron Agreement include (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. We 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 licenses granted by us can only provide benefit to Regeneron in combination with the research and development and manufacturing services provided by us, 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, we concluded all of the above promises are combined into a single performance obligation.

For revenue recognition purposes, we determine the term of our license or collaboration agreements by evaluating the period during which present and enforceable rights and obligations exist. This determination is impacted by the existence of substantive termination penalties, among other factors.

We recognize revenue under our license or collaboration agreements that are within the scope of ASC 606. These agreements include promises related to licenses to intellectual property and research and development services. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of

recognizing revenue from non-refundable, up-front fees. Accordingly, the transaction price is generally comprised of a fixed fee due at contract inception and at specified future dates, variable consideration in the form of milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. We measure the transaction price based on the amount of consideration to which we expect to be entitled in exchange for transferring the promised goods and/or services to the customer. We utilize the “most likely amount” method to estimate the amount of variable consideration to which we will be entitled for the contract. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes development and regulatory milestone payments, we evaluate whether the associated event is considered most likely to be achieved and estimates the amount to be included in the transaction price.

Payments or reimbursements for our research and development efforts where such efforts are considered part of or a single performance obligation are recognized over time using a measure of progress that best reflects our performance in satisfying the obligation and are presented on a gross basis.

Upfront payments are recorded as contract liabilities upon receipt or when due and may require deferral of revenue recognition to a future period until we perform our obligation under these arrangements. Amounts payable to us are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from the Regeneron Agreement.

Leases

We lease our facilities and, prior to December 31, 2019, we met the requirements to account for these leases as operating leases. We recognized rent expense on a straight-line basis over the non-cancelable lease term. Where leases contain escalation clauses, rent abatements or concessions, such as rent holidays and landlord or tenant incentives or allowances, we applied them in the determination of straight-line rent expense over the lease term.

As of December 31, 2019, we recorded the difference between the rent paid and the straight-line rent as a deferred rent liability. As of December 31, 2019, leasehold improvements funded by landlord incentives or allowances are recorded as leasehold improvement assets and a corresponding deferred rent liability. The leasehold improvement asset is amortized over the lesser of the term of the lease or life of the asset. The deferred rent liability is amortized on a straight-line basis as a reduction to rent expense over the term of the lease agreement.

Upon adoption of ASC 842, *Leases*, as described below under Recently Adopted Accounting Pronouncements, on January 1, 2020, we determined if an arrangement is a lease, or contains a lease, at inception. The asset component of our operating leases is recorded as right-of-use (ROU) assets, and the liability component is recorded as current lease liabilities and long-term lease liabilities in our consolidated balance sheets. ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As most of our leases do not provide an implicit rate, we use an incremental borrowing rate, which is the estimated rate we would be required to pay for a fully collateralized borrowing equal to the total lease payments over the term of the lease, to determine the present value of future minimum lease payments. The ROU asset also includes any lease payments made to the lessor at or before the commencement date, minus lease incentives received, and initial direct costs incurred. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of ASC 842, we do not combine lease and non-lease components. Variable lease payments are expenses as incurred.

Assumptions made by us at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

As a result of adopting ASC 842 in 2020, we recorded lease right-of-use, (ROU) asset of \$1.4 million and lease liabilities of \$1.8 million as of January 1, 2020, primarily related to office leases based on the present value of future lease payments. There was no impact to retained earnings upon the adoption of ASC 842. As of December 31, 2020, we did not record any finance leases.

Accrued CMO, CRO, and Research and Development Expenses

We have entered into various agreements with CMOs and CROs. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued and other current liabilities on the consolidated balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to CMOs and CROs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets on the consolidated balance sheets until the services are rendered. To date, our estimated accruals have not differed materially from the actual costs.

Stock-Based Compensation

We use a fair value-based method to account for all stock-based compensation arrangements with employees and non-employees, including stock options and restricted stock awards. Our determination of the fair value of stock options on the date of grant utilizes the Black-Scholes option pricing model. The fair value of the option granted is recognized on a straight-line basis over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period, which usually is the vesting period. We account for forfeitures as they occur. In determining fair value of the stock options granted, we use the Black-Scholes option-pricing model, which requires the input of subjective assumptions. These assumptions include estimating the length of time employees will retain their vested stock options before exercising them (expected term), the estimated volatility of our common stock price over the expected term (expected volatility), risk-free interest rate and expected dividends. Changes in the following assumptions can materially affect the estimate of fair value and ultimately how much stock-based compensation expense is recognized; and the resulting change in fair value, if any, is recognized in our consolidated statement of operations and comprehensive loss during the period the related services are rendered. These inputs are subjective and generally require significant analysis and judgment to develop. Changes in the following assumptions can materially affect the estimate of the fair value of stock-based compensation:

- **Expected Term** — The expected term is calculated using the simplified method which is used when there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.
- **Expected Volatility** — We use an average historical stock price volatility of a peer group of comparable publicly traded companies in biotechnology and pharmaceutical related industries to be representative of our expected future stock price volatility, as we do not have any trading history for our common stock. For purposes of identifying these peer companies, we consider the industry, stage of development, size and financial leverage of potential comparable companies. For each grant, we measure historical volatility over a period equivalent to the expected term.
- **Risk-Free Interest Rate** — The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term equivalent to the expected term of the stock award.
- **Expected Dividend Rate** — We have not paid and does not anticipate paying dividends in the near future. Accordingly, we estimate the dividend yield to be zero.

Common Stock Valuations

Prior to our Merger, the estimated fair value of the common stock underlying our stock options and stock awards was determined at each grant date by our board of directors, with assistance from management and external appraisers. All options to purchase shares of our common stock were intended to be exercisable at a price per share not less than the per-share fair value of our common stock underlying those options on the date of grant. The approach to estimate the fair value of our common stock was consistent with the methods outlined in the American Institute of Certified Public Accountants' Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation (Practice Aid). Subsequent to the Merger, the fair value of our common stock is determined based on the closing market price.

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 Annual Report on Form 10-K 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 Annual Report on Form 10-K for additional information.

Item 7A. 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 December 31, 2020, we had cash and cash equivalents and marketable debt securities of \$94.6 million, consisting of interest-bearing money market funds, asset-backed securities, corporate debt securities and commercial paper, 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 8. Financial Statements and Supplementary Data.

Our consolidated financial statements, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-43 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. 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 years ended December 31, 2020, 2019, and 2018, 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 years ended December 31, 2020, 2019 and 2018, 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 December 31, 2020. 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 December 31, 2020.

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 Annual Report on Form 10-K, 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 summarized below, which are either implemented or in the process of being implemented, are intended to address the identified material weaknesses.

- As a result of the Merger, we have inherited additional accounting personnel from resTORbio with appropriate experience, certification, education, and training with respect to the U.S. GAAP and standards issued by the PCAOB;
- We have engaged a permanent Vice President, Corporate Controller, whose primary responsibilities include working with third-party consultants to improve the design, implementation, execution, and supervision of our internal controls over financial reporting;
- We also appointed a full-time senior manager to oversee all aspects of technical accounting, SEC reporting, and Sarbanes-Oxley (SOX) requirements and compliances, including remediations;
- We implemented formal training of our accounting personnel responsible for preparation and review of account reconciliations and the posting and reviewing manual journal entries, to be held on a periodic basis, to ensure appropriate segregation of duties and improve internal controls over financial reporting; and
- We also implemented a new Enterprise Resource Planning (ERP) system, Microsoft 365 Business Central in January 2021, replacing Quickbooks and providing efficiency and financial controls. We will ensure appropriate training is offered to all key accounting personnel who are responsible for posting and reviewing journal entries. Training will be tailored specifically for the biotech industry to the extent applicable. Trainings will be formalized and held on a periodic basis as the Company hires more accounting personnel.

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 year ended December 31, 2020 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.

Exemption from Management's Report on Internal Control Over Financial Reporting for 2020

This annual report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly-public companies.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item regarding directors, executive officers and corporate governance will be included in our 2021 Proxy Statement, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K, and is incorporated herein by reference.

We have adopted a code of business conduct and ethics for directors, officers, and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at <http://www.adicetbio.com> under the Corporate Governance section of our Investors page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver. Shareholders may request a free copy of the Code of Business Conduct and Ethics from our Compliance Officer, c/o Adicet Bio, Inc., 500 Boylston Street, 13th Floor, Boston, MA 02116.

Item 11. Executive Compensation.

The information required by this item regarding executive compensation will be included in our 2021 Proxy Statement, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item regarding security ownership of certain beneficial owners and management and securities authorized for issuance under equity compensation plans will be included in our 2021 Proxy Statement, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item regarding certain relationships and related transactions and director independence will be included in our 2021 Proxy Statement, which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item regarding principal accounting fees and services will be included in our 2021 Proxy Statement, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K, and is incorporated herein by reference.

Item 15. Exhibits and Financial Statement Schedules.

The following documents are included in this Annual Report on Form 10-K:

- (1) The following Report and Consolidated Financial Statements of the Company are included in this Annual Report:
 - Report of Independent Registered Public Accounting Firm
 - Consolidated Balance Sheets
 - Consolidated Statements of Operations and Comprehensive Loss
 - Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
 - Consolidated Statements of Cash Flows
 - Notes to Consolidated Financial Statements
- (2) Financial Statement Schedules:
 - All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.
- (3) Exhibits. The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The Exhibit Index is incorporated herein by reference.

Item 16. 10-K Summary

We have elected not to include summary information.

ADICET BIO, INC.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Adicet Bio, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Adicet Bio, Inc. and subsidiaries (the Company) as of December 31, 2020, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for the year then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

We also have audited the adjustments described in Note 2 to retrospectively apply the exchange ratio to the 2019 and 2018 consolidated financial statements. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the 2019 or 2018 consolidated financial statements of the Company other than with respect to the adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2019 or 2018 consolidated financial statements taken as a whole.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for leases as of January 1, 2020 due to the adoption of Accounting Standards Update No. 2016-02, Leases (Topic 842).

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2020.

Boston, Massachusetts
March 11, 2021

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Adicet Bio, Inc.

Opinion on the Financial Statements

We have audited the consolidated balance sheet of Adicet Bio, Inc. and its subsidiary (the “Company”) as of December 31, 2019, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders’ equity (deficit), and of cash flows for each of the two years in the period ended December 31, 2019, including the related notes (collectively referred to as the “consolidated financial statements”), before the effects of the adjustments to retrospectively reflect the exchange ratio described in Note 2. In our opinion, the consolidated financial statements, before the effects of the adjustments to retrospectively reflect the exchange ratio described in Note 2, present fairly, in all material respects, the financial position of the Company as of December 31, 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America (the 2019 financial statements before the effects of the adjustments discussed in Note 2 are not presented herein).

We were not engaged to audit, review, or apply any procedures to the adjustments to retrospectively reflect the exchange ratio described in Note 2, and accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by other auditors.

Substantial Doubt About the Company’s Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred significant net operating losses and negative cash flows from operations since inception that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements, before the effects of the adjustments described above, based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements, before the effects of the adjustments described above, in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California
June 23, 2020

We served as the Company’s auditor from 2016 to 2020.

Adicet Bio, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 84,330	\$ 10,607
Short-term marketable debt securities	10,284	51,793
Prepaid expenses and other current assets	5,722	1,786
Total current assets	100,336	64,186
Property and equipment, net	2,790	2,121
Operating lease right-of-use asset	23,066	—
Goodwill	20,089	—
In-process research and development	1,190	—
Restricted cash	4,527	4,282
Long-term marketable debt securities	—	10,588
Other non-current assets	1,837	410
Total assets	\$ 153,835	\$ 81,587
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,552	\$ 1,052
Contract liabilities—related party, current	13,980	10,993
Accrued and other current liabilities	5,732	2,820
Operating lease liability	1,215	—
Total current liabilities	22,479	14,865
Contract liabilities—related party, net of current portion	—	10,890
Deferred rent, net of current portion	—	234
Operating lease liability, net of current portion	20,424	—
Redeemable convertible preferred stock warrant liability	—	1,881
Contingent consideration liability	980	—
Deferred tax liability	125	—
Total liabilities	44,008	27,870
Commitments and contingencies (Note 12)		
Redeemable convertible preferred stock, \$0.0001 par value; none and 99,363,444 shares authorized as of December 31, 2020 and 2019, respectively; none and 97,166,921 shares issued and outstanding as of December 31, 2020 and 2019, respectively; liquidation preference \$0 and \$128,195 as of December 31, 2020 and 2019, respectively	—	114,083
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized as of December 31, 2020 and 2019, respectively; none issued and outstanding as of December 31, 2020 and 2019, respectively	—	—
Common stock, \$0.0001 par value; 150,000,000 and 140,200,938 shares authorized as of December 31, 2020 and 2019, respectively; 19,677,249 and 2,155,578 shares issued and outstanding as of December 31, 2020 and 2019, respectively	2	—
Additional paid-in capital	216,126	9,258
Accumulated deficit	(106,325)	(69,647)
Accumulated other comprehensive income	24	23
Total stockholders' equity (deficit)	109,827	(60,366)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	\$ 153,835	\$ 81,587

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)

	Year ended December 31,		
	2020	2019	2018
Revenue—related party	\$ 17,903	\$ 995	\$ 8,181
Operating expenses:			
Research and development	34,334	23,691	14,717
General and administrative	22,760	8,692	8,428
Total operating expenses	57,094	32,383	23,145
Loss from operations	(39,191)	(31,388)	(14,964)
Interest income	785	938	543
Interest expense	(134)	—	—
Other income (expense), net	(953)	2,331	4,533
Loss before income tax benefit	(39,493)	(28,119)	(9,888)
Income tax expense (benefit)	(2,815)	19	(589)
Net loss	\$ (36,678)	\$ (28,138)	\$ (9,299)
Net loss per share attributable to common stockholders, basic and diluted	\$ (5.01)	\$ (13.15)	\$ (4.78)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	7,319,977	2,138,973	1,946,976
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable debt securities, net of tax	1	36	(13)
Total other comprehensive income (loss)	1	36	(13)
Comprehensive loss	\$ (36,677)	\$ (28,102)	\$ (9,312)

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)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at January 1, 2018	31,074,017	\$ 26,341	2,016,838	\$ —	\$ 5,262	\$ (32,210)	\$ —	\$ (26,948)
Issuance of Series A redeemable convertible preferred stock	9,020,833	10,825	—	—	—	—	—	—
Exercise of the redeemable convertible preferred stock tranche liability	—	902	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	123,949	—	221	—	—	221
Vesting of early exercised stock options	—	—	—	—	44	—	—	44
Stock-based compensation expense	—	—	—	—	2,479	—	—	2,479
Net loss	—	—	—	—	—	(9,299)	—	(9,299)
Unrealized loss on marketable securities	—	—	—	—	—	—	(13)	(13)
Balance at December 31, 2018	40,094,850	38,068	2,140,787	—	8,006	(41,509)	(13)	(33,516)
Issuance of Series A redeemable convertible preferred stock related to TRDF liability	67,656	88	—	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock, net of issuance cost of \$5,216	57,004,415	74,784	—	—	—	—	—	—
Termination of redeemable convertible preferred stock tranche liability	—	1,143	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	14,791	—	30	—	—	30
Vesting of early exercised stock options	—	—	—	—	47	—	—	47
Stock-based compensation expense	—	—	—	—	1,175	—	—	1,175
Net loss	—	—	—	—	—	(28,138)	—	(28,138)
Unrealized gain on marketable securities	—	—	—	—	—	—	36	36
Balance at December 31, 2019	97,166,921	114,083	2,155,578	—	9,258	(69,647)	23	(60,366)
Issuance of common stock upon exercise of stock options	—	—	210,752	1	459	—	—	460
Stock-based compensation expense	—	—	—	—	5,263	—	—	5,263
Conversion of shares of redeemable convertible preferred stock to shares of common stock in connection with the Merger	(97,166,921)	(114,083)	12,048,671	1	114,082	—	—	114,083
Exchange of common stock in connection with the Merger	—	—	5,207,695	—	83,516	—	—	83,516
Issuance of common stock upon accelerated vesting of restricted stock units in connection with the Merger	—	—	54,553	—	626	—	—	626
Conversion of redeemable convertible preferred stock warrants to common stock warrants	—	—	—	—	2,922	—	—	2,922
Net loss	—	—	—	—	—	(36,678)	—	(36,678)
Unrealized gain on marketable securities	—	—	—	—	—	—	1	1
Balance at December 31, 2020	—	\$ —	19,677,249	\$ 2	\$ 216,126	\$ (106,325)	\$ 24	\$ 109,827

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

Adicet Bio, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year ended December 31,		
	2020	2019	2018
Cash flows from operating activities			
Net loss	\$ (36,678)	\$ (28,138)	\$ (9,299)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization expense	1,226	1,238	1,222
Noncash lease expense	725	—	—
Stock-based compensation expense	5,263	1,175	2,479
Gain on disposal of property and equipment	—	(27)	—
Net amortization of premiums and accretion of discounts on investments	5	(197)	—
Change in fair value of redeemable convertible preferred stock tranche liability and TRDF liability	—	(2,024)	(4,536)
Change in fair value of redeemable convertible preferred stock warrant liability	897	(250)	—
Impairment of in-process research and development	2,300	—	—
Remeasurement of contingent consideration liability	(1,900)	—	—
Amortization of deferred debt issuance costs	134	—	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(3,233)	1,405	(2,825)
Other non-current assets	(1,260)	(88)	(302)
Accounts payable	(814)	527	(282)
Contract liabilities—related party	(7,903)	(995)	(3,181)
Deferred rent	—	(148)	(132)
Operating lease liabilities	(859)	—	—
Accrued and other current liabilities	787	(360)	(1,324)
Deferred tax liability	(242)	—	—
Net cash used in operating activities	<u>(41,552)</u>	<u>(27,882)</u>	<u>(18,180)</u>
Cash flows from investing activities			
Cash and restricted cash acquired in connection with the Merger	64,114	—	—
Purchases of marketable debt securities	(5,700)	(76,078)	(15,182)
Proceeds from maturities of marketable debt securities	57,793	29,099	—
Proceeds from sale of property and equipment	—	118	—
Purchase of property and equipment	(990)	(1,070)	(876)
Net cash provided by (used in) investing activities	<u>115,217</u>	<u>(47,931)</u>	<u>(16,058)</u>
Cash flows from financing activities			
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	76,915	10,825
Proceeds from exercise of stock options	460	30	221
Payment of debt issuance costs	(157)	—	—
Net cash provided by financing activities	<u>303</u>	<u>76,945</u>	<u>11,046</u>
Net change in cash, cash equivalents and restricted cash	73,968	1,132	(23,192)
Cash, cash equivalents and restricted cash, at the beginning of the period	14,889	13,757	36,949
Cash, cash equivalents and restricted cash, at the end of the period	<u>\$ 88,857</u>	<u>\$ 14,889</u>	<u>\$ 13,757</u>
Reconciliation of cash, cash equivalents and restricted cash to consolidated balance sheets:			
Cash and cash equivalents	\$ 84,330	\$ 10,607	\$ 9,475
Restricted cash	4,527	4,282	4,282
Cash, cash equivalents and restricted cash in consolidated balance sheets	<u>\$ 88,857</u>	<u>\$ 14,889</u>	<u>\$ 13,757</u>
Supplemental cash flow information			
Cash paid for income taxes	\$ 3	\$ 1	\$ 5,109
Cash received for income tax refunds	\$ 664	\$ —	\$ —
Supplemental disclosures of noncash investing and financing activities			
Purchase of property and equipment included in accounts payable	\$ 115	\$ 48	\$ 61
Right-of-use assets recognized upon adoption of ASC 842	\$ 1,424	\$ —	\$ —
Operating lease right-of-use asset obtained in exchange for operating lease liability	\$ 22,367	\$ —	\$ —
Issuance of redeemable convertible preferred stock warrants in connection with the Loan Agreement	\$ 144	\$ —	\$ —
Redeemable convertible preferred stock warrants issued in connection with issuance of Series B redeemable convertible preferred stock, net of issuance costs	\$ —	\$ 2,131	\$ —
Conversion of redeemable convertible preferred stock into common stock	\$ 114,083	\$ —	\$ —
Conversion of redeemable convertible preferred stock warrants into common stock warrants	\$ 2,922	\$ —	\$ —
Fair value of net assets acquired in Merger	\$ 84,142	\$ —	\$ —
Measurement period adjustment to goodwill	\$ 650	\$ —	\$ —
Vesting of early exercised stock options	\$ —	\$ 47	\$ 44
Exercise of redeemable convertible preferred stock tranche liability	\$ —	\$ —	\$ 902
Termination of redeemable convertible preferred stock tranche liability	\$ —	\$ 1,143	\$ —
Settlement of TRDF liability	\$ —	\$ 88	\$ —

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

Adicet Bio, Inc.
Notes to 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. 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. 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 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, resTORbio effected a reverse stock split of its 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 Former Adicet 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.

Adicet Bio, Inc.
Notes to Consolidated Financial Statements

Immediately following the Effective Time, there were approximately 19,589,828 shares of the Company's common stock outstanding (post Reverse Stock Split), with the former equity holders of Former Adicet holding approximately 75% of the outstanding shares of Company's common stock on a fully-diluted basis and the former equity holders of resTORbio holding 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 discussions of the Merger.

Liquidity and Going Concern

The Company has incurred significant net operating losses and negative cash flows from operations since inception and had an accumulated deficit of \$106.5 million as of December 31, 2020. The Company has historically financed its operations primarily through a collaboration and licensing arrangement, 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.

As of June 23, 2020, the issuance date of the Company's consolidated financial statements for the year ended December 31, 2019, the Company had concluded that there was substantial doubt about its ability to continue as a going concern. As of December 31, 2020, the Company had \$94.6 million in cash, cash equivalents, and marketable debt securities. In February 2021, the Company completed an underwritten public offering of 10,575,513 shares of its common stock, including the exercise in full by the underwriters of their option to purchase up to an additional 1,344,743 shares of common stock at a public offering price of \$13.00 per share. The 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. These two recent events have alleviated the substantial doubt about the Company's ability to continue as a going concern. 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 annual 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 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 or GAAP).

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. The U.S. dollar is the functional and reporting currency of the Company and its subsidiaries.

Exchange Ratio

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. Accordingly, all shares and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the Exchange Ratio.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the date of the consolidated financial statements as well as the reported amounts of revenues and expenses during the reporting period. Such estimates include the valuation of the intangible assets acquired in business combinations, redeemable convertible preferred stock warrant liability, redeemable convertible preferred stock tranche liability, the Technion Research and Development Foundation liability (TRDF Liability), contingent consideration liability for contingent value right (CVR), deferred tax assets, useful lives of property and equipment, accruals for research and development activities, revenue recognition and stock-based compensation and the Company's incremental borrowing rate. Actual results could differ from those estimates.

Business Combination

Business combinations are accounted for under the acquisition method. The Company recognizes the assets acquired and liabilities assumed in business combinations on the basis of their fair values at the date of acquisition. The Company assesses the fair value of assets acquired, including intangible assets, and liabilities assumed using a variety of methods. Each asset acquired and liability assumed is measured at fair value from the perspective of a market participant. The method used to estimate the fair values of intangible assets incorporates significant estimates and assumptions regarding the estimates a market participant would make in order to evaluate an asset, including a market participant's use of the asset, future cash inflows and outflows, probabilities of success, asset lives, and the appropriate discount rates. Acquired in-process research and development (IPR&D) is recognized at fair value and initially characterized as an indefinite-lived intangible asset, irrespective of whether the acquired IPR&D has an alternative future use. Any excess purchase price over the fair value of the net tangible and intangible assets acquired is allocated to goodwill. Transaction costs and restructuring costs associated with a business combination are expensed as incurred.

During the measurement period, which extends no later than one year from the acquisition date, the Company may record certain adjustments to the carrying value of the assets acquired and liabilities assumed with the corresponding offset to goodwill. After the measurement period, all adjustments are recorded in the consolidated statements of operations as operating expenses or income.

Contingent Consideration Liability (CVR)

The estimated fair value of the CVR, initially measured and recorded on the acquisition date, is considered to be a Level 3 instrument. The contingent consideration liability is recorded at fair value at the end of each reporting period with changes in estimated fair values recorded in research and development expenses in the consolidated statements of operations and comprehensive loss. The Company performed a remeasurement of the fair value of the CVR as of December 31, 2020 and recognized a gain of \$1.9 million in research and development expense in the statements of operations and comprehensive loss for the year ended December 31, 2020.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of net tangible and identified intangible assets acquired in a business combination. Goodwill is not amortized but is evaluated at least annually for impairment or when a change in facts and circumstances indicate that the fair value of the goodwill may be below the carrying value.

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Goodwill is tested for impairment at the reporting unit level annually in the fourth quarter, or more frequently when events or changes in circumstances indicate that the asset might be impaired. Examples of such events or circumstances include, but are not limited to, a significant adverse change in legal or business climate, an adverse regulatory action or unanticipated competition. The Company has determined that it operates in a single operating segment and has a single reporting unit.

Prior to performing the impairment test, the Company assesses qualitative factors to determine whether the existence of events or circumstances would indicate that it is more likely than not that the fair value of the reporting unit was less than the carrying amount. If after assessing the totality of events or circumstances, the Company were to determine that it is more likely than not that the fair value of the reporting unit is less than the carrying amount, then the Company would perform a quantitative impairment test.

The quantitative impairment test involves comparing the fair value of the reporting unit to the carrying value. If the fair value of the reporting unit exceeds the carrying value of the net assets, goodwill is not impaired, and no further testing is required. If the fair value of the reporting unit is less than the carrying value, the Company measures the amount of impairment loss, if any, as the excess of the carrying value over the fair value of the reporting unit. The Company performed an annual test for goodwill impairment in the fourth quarter of the fiscal year ended December 31, 2020 and determined that goodwill was not impaired.

Intangible Assets

In connection with the Merger, the Company acquired certain IPR&D assets, which were classified as indefinite-lived intangible assets. Acquired IPR&D represents the fair value assigned to research and development assets that the Company acquires and have not been completed at the acquisition date. The fair value of IPR&D acquired in a business combination is recorded on the Company's consolidated balance sheets at the acquisition-date fair value and is determined by estimating the costs to develop the technology into commercially viable products, estimating the resulting revenue from the products, and discounting the projected net cash flows to present value. IPR&D 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. The Company performed an annual review for impairment of IPR&D in the fourth quarter of the year ended December 31, 2020 and recognized an impairment charge of \$2.3 million as of December 31, 2020, which was recorded as research and development expenses in the consolidated statement of operations and comprehensive loss.

Segments

The Company operates and manages its business as one reportable and operating segment, which is the business of research and development of allogeneic immunotherapies for cancer and other diseases. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance.

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 Pharmaceuticals, Inc. (Regeneron), which represents 100% of the Company's total revenue during the years ended December 31, 2020, 2019 and 2018 (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.

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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 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.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with maturities of three months or less from the purchase date to be cash equivalents. As of December 31, 2020 and 2019, cash and cash equivalents consist of cash deposited with banks and investments in money market funds with maturities of three months or less from the date of purchase.

Marketable Debt Securities

Marketable debt securities are investments in marketable debt securities with maturities greater than three months at the time of purchase. The Company determines the appropriate classification of its investments in marketable debt securities at the time of purchase and reevaluates such designation at each balance sheet date. The Company has classified and accounted for its marketable debt securities as available-for-sale. The Company classifies highly liquid securities with maturities beyond 12 months as long-term marketable debt securities in the consolidated balance sheet. These securities are carried at fair value as determined based upon quoted market prices or pricing models for similar securities. Unrealized gains and losses, if any, are excluded from earnings and are reported as a component of accumulated other comprehensive income (loss). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income on the consolidated statements of operations and comprehensive loss. Realized gains and losses, if any, on available-for-sale securities are included in other income (expense), net. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income. The Company did not identify any of its marketable debt securities as other-than-temporarily impaired as of December 31, 2020 and 2019.

Restricted Cash

Restricted cash is comprised of cash that is restricted as to withdrawal or use under the terms of certain contractual agreements. Restricted cash for years ended December 31, 2020 and 2019 consists of collateral for letters of credit issued in connection with the real estate leases (see Note 12).

Fair Value of Financial Instruments

The carrying amounts of certain financial instruments of the Company, including cash equivalents, restricted cash, accounts payable and accrued and other current liabilities approximate fair value due to their relatively short maturities. The Company's marketable debt securities, CVR, redeemable convertible preferred stock warrant liability, redeemable convertible preferred stock tranche liability and TRDF Liability are carried at fair value (see Notes 4 and 5).

Redeemable Convertible Preferred Stock

The Company recorded all shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs, if applicable. The redeemable convertible preferred stock was recorded outside of permanent equity because while it was not mandatorily redeemable, in certain events considered not solely within the Company's control,

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such as a merger, acquisition or sale of all or substantially all of the Company's assets (each, a deemed liquidation event), the redeemable convertible preferred stock became redeemable at the option of the holders of at least a majority of the then outstanding shares. The Company has not adjusted the carrying values of the redeemable convertible preferred stock to its liquidation preference because a deemed liquidation event obligating the Company to pay the liquidation preferences to holders of shares of redeemable convertible preferred stock was not probable of occurring. All outstanding shares of redeemable convertible preferred stock converted into common stock upon Effective Time of the Merger.

Redeemable Convertible Preferred Stock Tranche Liability

The Company determined that its obligations to issue additional shares of redeemable convertible preferred stock upon the achievement of certain milestones or at the option of the respective holders of such shares represent freestanding financial instruments. These instruments were initially measured at fair value and were subject to remeasurement with changes in fair value recognized in other income (expense), net in the consolidated statements of operations and comprehensive loss until they were exercised, terminated, or settled (see Note 14).

Redeemable Convertible Preferred Stock Warrants

The Company's redeemable convertible preferred stock warrants required liability classification and accounting as the underlying redeemable convertible preferred stock was considered contingently redeemable and could have obligated the Company to transfer assets to the holders at a future date upon occurrence of a deemed liquidation event. The warrants were initially recorded at fair value upon issuance and were subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized in other income (expense), net in the consolidated statements of operations and comprehensive loss. Upon the closing of the Merger, pursuant to the Merger Agreement, all of the outstanding redeemable convertible preferred stock was converted to shares of the Company's common stock and the redeemable convertible preferred stock warrants converted to warrants for the purchase of the shares of the Company's common stock. Upon the closing of the Merger, the warrant liability was reclassified to additional paid-in capital (see Note 1).

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed on a straight-line basis over the estimated useful lives of the related assets, generally three years. Leasehold improvements are amortized using the straight-line method over the shorter of the assets' estimated useful lives or the remaining term of the lease. Maintenance and repairs are charged to operations as incurred. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheet and any resulting gain or loss is reflected in the consolidated statements of operations and comprehensive loss in the period realized.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. Recoverability is measured by comparison of the carrying amount of the asset or asset group to the future net cash flows which the asset or asset group is expected to generate. If such asset or asset group is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset or asset group exceeds the fair value of the asset or asset group. There has been no such impairment of long-lived assets during the years ended December 31, 2020 and 2019.

Revenue Recognition

Under ASC 606, *Revenue from Contracts with Customers* (ASC 606), the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps as prescribed by ASC 606:

- (i) identify the contract(s) with a customer;
- (ii) identify the performance obligations in the contract;
- (iii) determine the transaction price;
- (iv) allocate the transaction price to the performance obligations in the contract; and

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(v) recognize revenue when (or as) the Company satisfies a performance obligation.

A contract with a customer exists when (i) the Company enters into a legally enforceable contract with a customer that defines each party's rights regarding the products or services to be transferred and identifies the payment terms related to these products or services, (ii) the contract has commercial substance and (iii) the Company determines that collection of substantially all consideration for products or services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company identifies the goods or services promised and determines the performance obligations by assessing whether each promised good or service is distinct. Goods or services that are not distinct are bundled with other goods or services in the contract until a bundle of goods or services that is distinct is created. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

All of the Company's revenues are derived through a license and collaboration agreement (see Note 10).

For revenue recognition purposes, the Company determines the term of its license or collaboration agreements by evaluating the period during which present and enforceable rights and obligations exist. This determination is impacted by the existence of substantive termination penalties, among other factors.

The Company recognizes revenue under the Company's license or collaboration agreements that are within the scope of ASC 606. These agreements include promises related to licenses to intellectual property and research and development services. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. Accordingly, the transaction price is generally comprised of a fixed fee due at contract inception and at specified future dates, variable consideration in the form of milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. The Company measures the transaction price based on the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes the "most likely amount" method to estimate the amount of variable consideration to which it will be entitled for the contract. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes development and regulatory milestone payments, the Company evaluates whether the associated event is considered most likely to be achieved and estimates the amount to be included in the transaction price.

Payments or reimbursements for the Company's research and development efforts where such efforts are considered part of or a single performance obligation are recognized over time using a measure of progress that best reflects the Company's performance in satisfying the obligation.

Upfront payments are recorded as contract liabilities upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs its obligation under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from its collaboration arrangement.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including payroll and related expenses, costs for CMOs, costs for CROs, materials, supplies, depreciation on and maintenance of research equipment, consulting costs, and the allocated portions of facility costs, such as rent, utilities,

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insurance, repairs and maintenance, depreciation, information technology costs and general support services. All costs associated with research and development are expensed within the consolidated statements of operations and comprehensive loss as incurred.

Costs incurred in obtaining technology licenses are charged to research and development expense as acquired in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use.

Accrued CRO, CMO, and Research and Development Expenses

The Company has entered into various agreements with CMOs and CROs. The Company's research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced are included in accrued and other current liabilities on the consolidated balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made to CMOs and CROs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets on the consolidated balance sheets until the services are rendered. Through December 31, 2020 there had been no material adjustments to the Company's prior period estimates of accrued research and development expenses.

Leases

Effective January 1, 2020, the Company adopted ASC Topic 842, "Leases" (ASC 842), using the modified retrospective approach and utilizing the effective date as its date of initial application, for which prior periods are presented in accordance with the previous guidance in ASC Topic 840, "Leases" (ASC 840).

Prior to January 1, 2020, the Company met the requirements to account for these leases as operating leases under ASC 840. The Company recognized rent expense on a straight-line basis over the non-cancelable lease term. Where leases contained escalation clauses, rent abatements or concessions, such as rent holidays and landlord or tenant incentives or allowances, the Company applied them in the determination of straight-line rent expense over the lease term. As of December 31, 2019, the Company recorded the difference between the rent paid and the straight-line rent as a deferred rent liability. The leasehold improvements funded by landlord incentives or allowances were recorded as leasehold improvement assets and a corresponding deferred rent liability. The leasehold improvement asset was amortized over the lesser of the term of the lease or life of the asset. The deferred rent liability was amortized on a straight-line basis as a reduction to rent expense over the term of the lease agreement.

Upon adoption of ASC 842, as described below under Recently Adopted Accounting Pronouncements, the Company determined if an arrangement is a lease, or contains a lease, at inception. Leases with a term greater than 12 months are recognized on the balance sheet as Right-of-Use (ROU) assets and current and long-term operating lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The Company monitors its plan to renew its leases no less than on a quarterly basis. In addition, the Company's lease agreements generally do not contain any residual value guarantees or restrictive covenants.

In accordance with ASC 842, the ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate (IBR), which is the estimated rate the Company would be required to pay for a fully collateralized borrowing equal to the total lease payments over the term of the lease, to determine the present value of future minimum lease payments. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of ASC 842, the Company does not combine lease and non-lease components. Variable lease payments are expenses as incurred.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

Upon the adoption of ASC 842, the Company recognized an ROU asset of \$1.4 million and lease liabilities of \$1.8 million as of January 1, 2020, primarily related to office leases based on the present value of future lease payments. As of December 31, 2020, the Company has recorded an ROU asset of \$23.1 million and lease liabilities of \$21.6 million on its consolidated

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balance sheets. There was no impact to retained earnings upon the adoption of ASC 842. As of December 31, 2020, the Company had no finance leases.

Fair Value of Common Stock

Prior to the Merger the fair value of the Company's common stock was determined by its Board of Directors with input from management and third-party valuation specialists. The Company's approach to estimate the fair value of the Company's common stock is consistent with the methods outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Determining the best estimated fair value of the Company's common stock requires significant judgement and management considers several factors, including the Company's stage of development, equity market conditions affecting comparable public companies, significant milestones and progress of research and development efforts. Subsequent to the Merger, the fair value of the Company's common stock is determined based on its closing market price.

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees and non-employees using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments including stock options. The fair value method requires the Company to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. The Company uses the Black-Scholes option-pricing model to estimate the fair value of options granted that are expensed on a straight-line basis over the requisite service period, which is generally the vesting period. The Company accounts for forfeitures as they occur. Option valuation models, including the Black-Scholes option-pricing model, require the input of several assumptions. Changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences attributable to differences between carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax reporting purposes and for operating loss and tax credit carryforwards. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company's deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which these temporary differences are expected to be recovered or settled. A valuation allowance is recorded to reduce deferred tax assets if it is determined that it is more likely than not that all or a portion of the deferred tax asset will not be realized. The Company considers many factors when assessing the likelihood of future realization of deferred tax assets, including recent earnings results, expectations of future taxable income, carryforward periods available and other relevant factors. The Company records changes in the required valuation allowance in the period that the determination is made.

The Company assesses its income tax positions and records tax benefits for all years subject to examination based upon management's evaluation of the facts, circumstances and information available as of the reporting date. For those tax positions where it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, the Company does not recognize a tax benefit in the consolidated financial statements. The Company records interest and penalties related to uncertain tax positions, if applicable, as a component of income tax expense (benefit).

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. The other comprehensive loss disclosed in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2020, 2019 and 2018 consists of changes in unrealized gains and losses on marketable debt securities.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-

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average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the redeemable convertible preferred stock, redeemable convertible preferred stock warrants, redeemable convertible preferred stock tranche liability, common stock subject to repurchase and stock options are considered to be potentially dilutive securities. Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock and early exercised stock options are considered to be participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income (loss) available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in undistributed earnings as if all income (loss) for the period had been distributed. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss is attributed entirely to common stockholders. Since the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB under its ASC 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 February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842) (ASC 842)*, which sets out the principles for the recognition, measurement, presentation, and disclosure of leases for both parties to a contract (i.e. lessees and lessors). In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842, Leases*, which provides clarification to ASU 2016-02. In March 2019, the FASB issued ASU 2019-01, which provides clarification on implementation issues associated with adopting ASU 2016-02. These ASUs (collectively the new leasing standard) requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a ROU and a lease liability for all leases with a term of greater than 12 months regardless of their classification. ASC 842 provides a lessee with an option to not account for leases with a term of 12 month or less as leases in the scope of ASC 842. ASC 842 supersedes the previous leases standard, ASC 840 *Leases*. The new leasing standard is effective for public business entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, and should be applied through a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. Early adoption is permitted. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which allows entities to elect an optional transition method where entities may continue to apply the existing lease guidance during the comparative periods and apply the new lease requirements through a cumulative effect adjustment in the period of adoptions rather than in the earliest period presented. In June 2020, the FASB issued ASU 2020-05, which delays the adoption dates for ASU 2016-02 for non-public entities to fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early application continues to be allowed.

The Company adopted ASC 842 effective January 1, 2020, using the modified retrospective approach to recognize a cumulative-effect adjustment as of the adoption date. Results for reporting periods beginning after January 1, 2020 are presented under ASC 842, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historical accounting under ASC 840. The Company elected the package of practical expedients permitted under the transition guidance within ASC 842, which allowed the Company to carry forward the historical lease classification, retain the initial direct costs for any leases that existed prior to the adoption of the standard and not reassess whether any contracts entered into prior to the adoption are leases. The Company also elected to account for lease and non-lease components in the Company's lease agreements as a single lease component in determining lease assets and liabilities. In addition, the Company elected not to recognize the ROU assets and liabilities for leases with lease terms of 12 months or less. Upon the adoption of ASC 842, the Company recognized an ROU asset of \$1.4 million and lease liabilities of \$1.8 million as of January 1, 2020, primarily related to office leases based on the present value of future lease payments. The adoption of the new leasing standard during 2020 resulted in the recognition of ROU asset of \$23.1 million and operating lease liability of \$21.6 million and derecognition of deferred rent of \$0.4 million related to the operating leases on the consolidated balance sheets as of December 31, 2020 with no material impact to the consolidated statements of operations and comprehensive loss, consolidated statements of redeemable convertible preferred stock and stockholder's deficit or consolidated statements of cash flows. The additional disclosures required by the new standard have been included in Note 12, Commitments and Contingencies.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements on fair value measurements. The new disclosure requirements include disclosure related to changes in unrealized gains or losses

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included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of each reporting period and the explicit requirement to disclose the range and weighted-average of significant unobservable inputs used for Level 3 fair value measurements. This ASU removes the requirement to disclose: the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; the policy for timing of transfers between levels; and the valuation processes for Level 3 fair value measurements. For all entities, this ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted this ASU effective January 1, 2020. The adoption of this ASU did not have a material effect on the Company's consolidated 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 Securities and Exchange Commission (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 November 2018, FASB issued 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 is currently evaluating the impact the adoption of this ASU will have on its consolidated financial statements and related disclosures.

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 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.

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resTORbio's stockholders continued 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 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.

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 common shares	<u>86,396</u>
Acceleration of 54,553 shares of restricted stock units upon merger (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>

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- 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 (post-reverse stock split) of resTORbio common stock outstanding as of September 15, 2020.
 - b. The fair value of shares of the combined company owned by resTORbio stockholders 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 received 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.

During the fourth quarter of 2020, the Company identified and recorded measurement period adjustments of \$0.7 million to its preliminary purchase price allocation that was disclosed in prior periods based on the facts and circumstances existing as of the acquisition date.

The following summarizes the allocation of the purchase price to the net tangible and intangible assets acquired at the date of acquisition both as disclosed in the Company's quarterly report on Form 10-Q as of September 30, 2020 and as adjusted for measurement period adjustments identified during the fourth quarter of 2020 (in thousands):

	As of September 15, 2020 (preliminary)	Measurement Period Adjustments	As of December 31, 2020 (as adjusted)
Net assets acquired:			
Cash and cash equivalents	\$ 63,869	\$ —	\$ 63,869
Prepaid expenses and other current assets	2,505	554	3,059
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	(2,421)	56	(2,365)
Other liabilities	(40)	40	—
Deferred tax liability	(367)	—	(367)
Goodwill	20,739	(650)	20,089
Purchase price	<u>\$ 87,022</u>	<u>\$ —</u>	<u>\$ 87,022</u>

The goodwill of \$20.1 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 IPR&D 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

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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 are 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.

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.

Transaction costs for the Merger were \$7.1 million for the year ended December 31, 2020 and were expensed as incurred in general and administrative expenses in the consolidated statements of operations and comprehensive loss.

The following supplemental unaudited pro forma information represents the Company's financial results as if the acquisition of resTORbio had occurred on January 1, 2019 (in thousands).

	For the Year Ended December 31,	
	2020	2019
Revenue - related party	\$ 17,903	\$ 995
Net loss	\$ (35,757)	\$ (113,151)

The above unaudited pro forma information was determined based on the historical GAAP results of the Company and resTORbio. The unaudited pro forma consolidated results are not necessarily indicative of what the Company's consolidated results of operations would have been if the acquisition was completed on January 1, 2019. The unaudited pro forma consolidated net loss includes pro forma adjustments of \$15.6 million primarily relating to the reclassification of transaction costs, severance payments and stock-based compensation expense directly related to the closing of the Merger from the year ended December 31, 2020 to the year ended December 31, 2019. The unaudited proforma information include proforma adjustments to eliminate the impact of the change in the fair value of the TRDF liability during the year ended December 31, 2019, and the redeemable convertible preferred stock tranche liability and redeemable convertible warrant liability during the years ended December 31, 2020 as the redeemable convertible preferred stock tranche liability, TRDF liability, and redeemable convertible warrant liability did not exist once the redeemable convertible preferred stock were converted to common stock in the Merger. The unaudited proforma information also includes proforma adjustments to reclassify stock compensation expense related to the conversion of resTORbio stock options and restricted stock units and the modification of stock option awards to Former Adicet CEO in connection with the Merger to January 1, 2019. Further, stock compensation expense related to resTORbio stock options and restricted stock units recognized in the books of resTORbio prior to the Merger in 2019 and 2020 was reversed in the proforma information.

Former Chief Executive Officer's Transition Agreement

On April 28, 2020, in connection with the Merger the Company entered into a transition agreement with Anil Singhal, Former Adicet's Chief Executive Officer and President, pursuant to which Dr. Singhal transitioned from his role as Chief Executive Officer and President to an advisory role immediately after the closing of the Merger. In accordance with such agreement, Dr. Singhal was entitled to the following compensation: (1) cash payments of (i) \$470,000 within 60 days

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following the closing of the Merger, (ii) an amount equal to his pro-rated bonus of \$212,000 for the 2020 calendar year payable within 60 days following the closing of the Merger, (iii) \$250,000 payable in one lump sum on January 1, 2021 and (iv) \$24,000 payable within 60 days following the closing of the Merger, (2) 12 months' of accelerated vesting of his unvested options to purchase the Company's common stock upon completion of the Merger, and (3) a 12-month post-termination exercise period following termination of his independent contractor services agreement, dated April 28, 2020 (the ICSA), subject to any earlier expiration of the options to purchase the Company's common stock by their terms. In addition, Dr. Singhal is entitled to reimbursement of up to \$15,000 of his reasonable and documented legal expenses incurred in connection with such transition agreement. Pursuant to such agreement, subject to Dr. Singhal's continued service through the completion of the Merger and contingent on completion of the Merger, Dr. Singhal's continued service for purposes of vesting of his options to purchase the Company's common stock will continue until the earlier of (i) May 7, 2021 or (ii) termination of the ICSA, provided, however, if the ICSA is terminated early without cause, Dr. Singhal is entitled to accelerated vesting of unvested options that would have vested from the date of such termination through May 7, 2021. In addition, Dr. Singhal's existing options acceleration provisions will terminate. Pursuant to the ICSA, Dr. Singhal will provide certain advisory services to the Company for a term of 12 months following the closing of the Merger and is entitled to payments of \$12,500 per month for such services. The ICSA was terminated without cause in February 2021.

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):

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds(1)	\$ 63,817	\$ —	\$ —	\$ 63,817
Marketable debt securities				
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

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	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds ⁽¹⁾	\$ 7,232	\$ —	\$ —	\$ 7,232
Marketable debt securities				
Asset-backed securities	—	19,598	—	19,598
Corporate debt securities	—	19,394	—	19,394
Commercial paper	—	17,892	—	17,892
U.S. Government agency bonds	—	5,497	—	5,497
Marketable debt securities	—	62,381	—	62,381
Total fair value of assets	\$ 7,232	\$ 62,381	\$ —	\$ 69,613
Liabilities:				
Redeemable convertible preferred stock warrant liability	\$ —	\$ —	\$ 1,881	\$ 1,881
Total fair value of liabilities	\$ —	\$ —	\$ 1,881	\$ 1,881

(1) Included in cash and cash equivalents 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.

The following table presents a summary of the changes in the fair value of the Company's Level 3 financial instrument (in thousands):

	Redeemable Convertible Preferred Stock Tranche Liability	TRDF Liability	Redeemable Convertible Preferred Stock Warrant Liability	Contingent Consideration Liability
Fair value as of January 1, 2018	\$ 8,557	\$ 136	\$ —	\$ —
Change in the fair value included in other income (expense), net	(4,542)	6	—	—
Exercise	(902)	—	—	—
Fair value as of December 31, 2018	3,113	142	—	—
Recognition of preferred stock warrant liabilities	—	—	2,131	—
Settlement	—	(88)	—	—
Change in the fair value included in other income (expense), net	(1,970)	(54)	(250)	—
Termination	(1,143)	—	—	—
Fair value as of December 31, 2019	—	—	1,881	—
Recognition of preferred stock warrant liability	—	—	144	—
Recognition of contingent consideration liability	—	—	—	2,880
Change in the fair value included in other income (expense), net	—	—	897	—
Change in the fair value included in research and development expense	—	—	—	(1,900)
Conversion of convertible preferred stock warrant into common stock warrant in connection with Merger	—	—	(2,922)	—
Fair value as of December 31, 2020	\$ —	\$ —	\$ —	\$ 980

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The fair value of the redeemable convertible preferred stock tranche liability, TRDF Liability, the redeemable convertible preferred stock warrant liability is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy.

The Company determined that the obligations to issue additional shares of Series A redeemable convertible preferred stock at the Milestone Closing and Additional Closing were freestanding instruments that are required to be accounted as a liability initially recorded and subsequently remeasured at fair value until such instruments are exercised or expire. The Milestone Closing liability and Additional Closing liability were initially recorded at \$6.2 million and \$5.0 million, respectively.

The Milestone Closing liability was settled in November 2018 upon the Milestone Closing and the related TRDF liability was settled in March 2019. In July 2019, as part of the Series B redeemable convertible preferred stock purchase agreement the Additional Closing liability and the related TRDF liability were terminated. The Company recorded \$2.0 million gain from the remeasurement of the redeemable convertible preferred stock tranche liability associated with the Additional Closing and termination in other income (expense), net in its consolidated statements of operations and comprehensive loss during the year ended December 31, 2019.

There were no warrants outstanding for the purchase of redeemable convertible preferred stock as of December 31, 2020, as all such warrants were converted to warrants for the purchase of shares of common stock upon the Merger.

The fair value of the TDRF Liability was determined based on the fair value of the Company's Series A redeemable Preferred stock.

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 November 2020, management terminated the nursing home study due to poor enrollment and consequently lowered the probability of finding a partner due to the delay in time to commercialization of RTB101. As a result, the fair value of the CVR liability decreased by \$1.9 million to \$1.0 million.

5. Marketable Debt Securities

The following tables summarize the Company's marketable debt securities (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	\$ 10,260	\$ —	\$ 24	\$ 10,284

	December 31, 2019			
	Amortized Cost	Unrealized Losses	Unrealized Gains	Fair Value
Asset-backed securities	\$ 19,589	\$ (1)	\$ 10	\$ 19,598
Corporate debt securities	19,387	(3)	9	19,393
Commercial paper	17,882	—	11	17,893
U.S. Government agency bonds	5,500	(3)	—	5,497
Total	\$ 62,358	\$ (7)	\$ 30	\$ 62,381

The following table summarizes the Company's marketable debt securities by contractual maturity (in thousands):

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	December 31, 2020	
	Amortized Cost	Fair Value
Within one year	\$ 10,260	\$ 10,284
After one year through five years	—	—
After five years	—	—
Total	\$ 10,260	\$ 10,284

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

	December 31	
	2020	2019
Short-term marketable debt securities	\$ 10,284	\$ 51,793
Long-term marketable debt securities	—	10,588
Total	\$ 10,284	\$ 62,381

6. Prepaid Expenses and Other Current Assets

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

	December 31	
	2020	2019
Prepaid maintenance and other	\$ 1,185	\$ 615
Prepaid insurance	1,443	57
Tax receivable	2,711	722
Interest receivable	20	213
Other current assets	363	179
Total	\$ 5,722	\$ 1,786

7. Property and Equipment, net

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

	Useful life (years)	As of December 31,	
		2020	2019
Laboratory equipment	3	\$ 4,350	\$ 3,872
Leasehold improvements	Lesser of useful life or lease term	1,427	1,327
Furniture and fixtures	3	524	68
Construction in progress	—	1,090	300
Computer equipment	3	93	42
Software	3	170	150
		7,654	5,759
Less: Accumulated depreciation and amortization		(4,864)	(3,638)
Property and equipment, net		\$ 2,790	\$ 2,121

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Depreciation and amortization expense for each of the years ended December 31, 2020, 2019 and 2018 was \$1.2 million. All of the Company's property and equipment as of December 31, 2020 and 2019 is located in the U.S.

8. Accrued and Other Current Liabilities

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

	December 31	
	2020	2019
Accrued compensation	\$ 3,833	\$ 1,359
Accrued research and development expenses	1,187	450
Accrued professional services	386	301
Accrued other liabilities	326	710
Total	\$ 5,732	\$ 2,820

9. Term Loan

On April 28, 2020, the Company 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 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%. The Loan Agreement granted to Pacific Western Bank a security interest on substantially all of the Company's assets other than intellectual property to secure the performance of the Company's obligations under the Loan Agreement, and contains a variety of affirmative and negative covenants, including required financial reporting, limitations on certain dispositions of assets or distributions, limitations on the incurrence of additional debt or liens and other customary requirements. As of December 31, 2020, the Company was in compliance with such covenants and had no indebtedness outstanding under the Loan Agreement.

In connection with the entrance into the Loan Agreement, the Company issued Pacific Western Bank a warrant to purchase shares of its Series B redeemable convertible preferred stock at an exercise price of \$1.4034 per share (the Existing PacWest Warrant). The Existing PacWest Warrant was initially exercisable for 42,753 shares of the Company's Series B redeemable convertible preferred stock (not adjusted for the Exchange Ratio). Pursuant to the terms of the Existing PacWest Warrant and the Merger agreement (see Note 3), at the Effective Time of the Merger, the Company issued a new common stock warrant to Pacific Western Bank (the New PacWest Warrant) which replaced the Existing PacWest Warrant. The New PacWest Warrant is initially exercisable solely for 5,301 shares of the Company's common stock and will be exercisable for an additional number of shares of the Company's 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 the Company's common stock). Any restriction on the exercise set forth in the Existing PacWest Warrant are in full force and effect in the New PacWest Warrant and the term, exercisability, vesting schedule and other provisions of the Existing PacWest warrant otherwise remain unchanged in the New PacWest Warrant. Further, the New PacWest Warrant to purchase 5,301 shares of the Company's common stock is immediately exercisable. See Note 15 for further discussion regarding terms of warrants. The New PacWest Warrant was exercised in February 2021.

The Company may request to draw upon the term loan at any time through the date eighteen months after the date of the Loan Agreement (Availability End Date), which is October 28, 2021. As of December 31, 2020, no amounts have been drawn under the Loan Agreement.

At issuance, the Company accounted for the fair value of the Existing PacWest Warrant, determined to be \$0.1 million, as a liability and as a corresponding deferred debt issuance cost which was amortized on a straight-line basis until the Availability End Date in interest expenses. The liability was adjusted to fair value each reporting period through earnings. Upon issuance of the New PacWest Warrant, the liability was reclassified to additional paid-in capital and is no longer subject to remeasurement at fair value. The fair value of the New PacWest Warrant was equal to the fair value of the Existing PacWest Warrant on the Merger date. Accordingly, no incremental expense was recognized at the Merger date.

Upon each draw of the term loan, the Company will derecognize the proportionate unamortized amount of the deferred asset and account for it as a debt discount to the drawn term loan. The debt discount will be presented in the consolidated balance sheet as a direct adjustment to the carrying value of the term loan. The debt discount will be amortized using the effective interest rate method over the term of the debt and recorded as an interest expense.

As of December 31, 2020, the deferred debt issuance costs were \$0.2 million and are included in other non-current assets on the Company's consolidated balance sheets.

10. Regeneron License and Collaboration Arrangement

Agreement Terms

On July 29, 2016, the Company entered into a license and collaboration agreement with Regeneron Pharmaceuticals, Inc. (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).

Agreement Structure. The Regeneron Agreement has two principal components: (a) a research collaboration component under which the parties will research, develop, and commercialize next-generation engineered gamma delta immune cell therapeutics (ICPs), namely engineered gamma delta immune cells with CARs and TCRs directed to disease-specific cell surface antigens, which includes the grant of certain licenses to intellectual property between the two parties, and (b) for a certain period following the effective date, a license to the Company to use certain of Regeneron's proprietary mice to develop and commercialize ICPs generated by the Company, with certain limitations relating to targets under the Regeneron Agreement.

Research Collaboration. Research activities under the collaboration are governed by research plans, which include the strategy, goals, activities, and responsibilities of the parties with respect to a target. The Company is primarily responsible for generating, validating, and optimizing ICPs, developing processes for manufacture of ICPs, and certain preclinical and clinical manufacturing activities for ICPs; Regeneron's key responsibility is generating, validating, and optimizing CARs and TCRs that bind to the applicable target. The parties have formed a joint research committee to monitor and govern the research and development efforts during the research program term.

Rights to Research Targets. Under the terms of the five-year research collaboration, the parties will conduct research on mutually agreed upon targets. Regeneron may obtain exclusive rights for the targets that it chooses in accordance with the target selection mechanism set forth in the Regeneron Agreement, and the Company similarly may obtain exclusive rights for targets it chooses in accordance with such target selection mechanism. The Company has the right to develop and commercialize ICPs to the first collaboration target to come out of the research program. In connection with an IND submission, Regeneron has an option to exercise exclusive rights for ADI-002 and potentially for additional targets to be mutually agreed upon. For those targets it does not have an option to license, Regeneron has a right of first negotiation for up to two targets. Regeneron has the right to terminate the research program in its entirety (a) for convenience on six months prior written notice given at any time after December 31, 2019, or (b) following a change of control (as defined in the Regeneron Agreement) of the Company. The parties mutually agreed to their first product declaration criteria for collaboration ICP, CD20, in 2018.

Rights to Company-Developed Targets. Regeneron has an exclusive license to use targeting moieties generated by the Company by its use of Regeneron's proprietary mice to develop and commercialize non-ICPs.

Exclusivity. During the five-year target selection period, the Company may not directly or indirectly research, develop, manufacture or commercialize an ICP, or grant a license to do the foregoing, except pursuant to the agreement. For so long as either party is researching or developing an ICP to a target under the research program, neither party may research, develop, manufacture or commercialize any other ICP to such target, or grant a license to do the foregoing. And for so long as a party is researching, developing or commercializing an ICP to target that is licensed to it (and royalty bearing) under the agreement, neither party may research, develop, manufacture or commercialize any other ICP to such target, or grant a license to permit another party to do the foregoing. These exclusivity obligations are limited to engineered gamma delta immune cells to targets reasonably considered to have therapeutic relevance in oncology. The Regeneron Agreement includes certain exceptions to the exclusivity obligations of the parties, including with respect to targets that are rejected by one party in the target selection process, as well as protections in the event of a change of control of a party where the acquirer has a competing program.

Co-Funding and Profit Sharing. The Company has an option to co-fund specified portions of the future development costs for, and to co-promote, ICPs to a target for which Regeneron has exercised an option, and to participate in the profits for such target. The Company has the right to exercise this right in various geographic regions, including on a worldwide basis. In the event the Company exercises such right, the parties will share further development costs and revenues proportionally to their co-funding percentages.

Financial Terms. The Company received a non-refundable upfront payment of \$25.0 million from Regeneron upon execution of the Regeneron Agreement, has received an aggregate of \$20.0 million of additional payments for research funding from Regeneron as of December 31, 2020. 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.

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Other Terms. The Regeneron Agreement contains customary representations, warranties and covenants by the Company and Regeneron and includes (i) an obligation of the Company to use commercially reasonable efforts to develop and commercialize at least one product based on a collaboration ICP that is not an optioned collaboration ICP for each collaboration target and (ii) an obligation of Regeneron to use commercially reasonable efforts to develop and commercialize at least one product based on an optioned collaboration ICP for each collaboration target. The Company and Regeneron are required to indemnify the other party against all losses and expenses related to breaches of its representations, warranties and covenants under the Regeneron Agreement.

Term and Termination. The term of the Regeneron Agreement expires, on a product-by-product basis, on the expiration of the obligation to pay royalties for such product. The Regeneron Agreement is subject to early termination by either party upon uncured material breach by the other party. The licenses to develop and commercialize an ICP to a target that one party has exclusively licensed may be terminated by such party for convenience.

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.

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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 also considered the existence of any significant financing component within the Regeneron Agreement given its upfront payment structure. Based upon this assessment, the Company concluded that the up-front payment was provided for valid business reasons and not for the purpose of providing financing. The reason for the initial advance payment at the beginning of the contract is not to provide financing to the Company, but to ensure Regeneron's commitment to the contract and to provide assurance that the customer will perform its obligations under the contract. Accordingly, the Company has concluded that the upfront payment structure of the Regeneron Agreement does not result in the existence of a significant financing component.

The royalty payments will be recognized when the related sales occur as they were determined to relate predominantly to the intellectual property licenses granted to Regeneron and therefore have also been excluded from the transaction price.

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. 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 table presents changes in the Company's contract liabilities (in thousands):

Year ended December 31, 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	\$ (17,903)	\$ 13,980
Year ended December 31, 2019	Balance at beginning of period	Additions	Additions (Deductions) (1)	Balance at end of period
Contract liability	\$ 22,878	\$ —	\$ (995)	\$ 21,883

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

Contract assets are 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.

Contract liabilities related to the Regeneron Agreement of \$14.0 million and \$21.9 million as of December 31, 2020 and 2019, respectively, which 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 \$31.0 million and \$13.1 million of license and collaboration revenue recognized from the inception of the Regeneron Agreement as of December 31, 2020 and 2019, respectively, will be recognized as the combined performance obligation is satisfied.

During the years ended December 31, 2020, 2019 and 2018, the Company recognized \$17.9 million, \$1.0 million and \$8.2 million of license and collaboration revenue, respectively, from amounts included in the contract liability balances at the beginning of the period. There were no costs to obtain or fulfill the contract that meet the criteria to be capitalized.

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 poor enrollment and as a consequence lowered the probability of finding a partner due to the delay in time to commercialization of RTB101. As a result, the fair value of the CVR liability was decreased by \$1.9 million to \$1.0 million.

Novartis License Agreement

On March 23, 2017, resTORbio entered into an exclusive license agreement with Novartis International Pharmaceutical Ltd. (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.

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. As of December 31, 2020, none of the remaining clinical milestones, regulatory milestones, sales milestones, or royalties had been reached or were probable of achievement.

National Institute of Health

In May 2019, resTORbio 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. resTORbio is entitled to use the award solely to conduct the research and is solely responsible for commencing and conducting the research and will furnish periodic progress

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updates to the NIH throughout the term of the award. After completing the research, resTORbio 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, resTORbio 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 resTORbio in advance of funding by the NIH are recorded in the consolidated balance sheets as other current assets. For the year ended December 31, 2020, \$0.7 million qualifying expenses have been incurred and \$0.6 million have been funded by the NIH.

12. Commitments and Contingencies

Operating Leases

On September 30, 2015, the Company entered into a lease agreement (the Menlo Park Lease) to lease approximately 17,352 square feet of office and laboratory space located in Menlo Park, CA. The total base lease payments over the life of the lease are \$3.4 million, offset by \$0.8 million in tenant improvement allowances. The lease expires on March 31, 2022. The landlord maintains responsibility for maintenance and risk of loss throughout the term of the lease agreement. The lease is recorded as an operating lease.

On September 30, 2019 and October 19, 2020, the Company entered into amendments to the Menlo Park lease agreement for the office and laboratory space in Menlo Park to lease from the same landlord additional nearby buildings with approximately 7,973 and 4,862 square feet of office and laboratory space, respectively. The leases commenced on October 1, 2019 and October 1, 2020, respectively, and both amendment leases expire on March 31, 2022. The total base lease payments over the life of the lease amendments are \$0.4 million and \$0.3 million, respectively.

On October 28, 2018, the Company entered into a new lease agreement to lease approximately 50,305 square feet of office and laboratory space located in Redwood City, CA. The total base lease payments over the life of the lease are \$29.5 million, offset by \$3.0 million in tenant improvement allowances. On December 30, 2020, the Company entered an amendment to the Redwood City lease to change the manner in which tenant improvements will be constructed at the premises. The lease has not commenced as the office and laboratory space is not available for use by the Company. The lease expires on February 28, 2030.

In April 2019, the Company amended its multi-year lease agreement to relocate its office space in Boston, MA under an operating lease agreement. The amended lease term is for a period of seven years from the date of relocation on August 1, 2019. The total base lease payments over the remaining lease term are \$3.5 million.

The Company recognized rent expense of \$0.9 million, \$0.7 million and \$0.5 million for the years ended December 31, 2020, 2019 and 2018, respectively.

As a result of adopting ASC 842 in 2020, the Company recorded lease right-of-use, (ROU) asset of \$1.4 million and lease liabilities of \$1.8 million as of January 1, 2020, primarily related to office leases based on the present value of future lease payments. There was no impact to retained earnings upon the adoption of ASC 842. As of December 31, 2020, the Company had no finance lease.

The adoption of ASC 842 resulted in the recognition of an operating lease ROU asset and corresponding liability in 2020 based on the present value of remaining lease payments discounted at the Company's estimated IBR. The IBR and the remaining lease terms of our facilities and their weighted average IBR and remaining terms are as follows as of December 31, 2020:

<u>Lease Locations</u>	<u>IBR</u>	<u>Remaining Terms (in years)</u>
Redwood City, CA	6.90%	9.2
Boston, MA	9.30%	5.6
Menlo Park, CA	6.80%	1.3
Weighted Average	7.20%	8.4

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The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating leases for the year ended December 31, 2020:

	For the Year Ended December 31, 2020	
Lease Cost	(in thousands)	
Operating lease cost	\$	894
Short-term lease cost		56
Variable lease cost		—
Total lease cost	\$	<u>950</u>
Other Information		
Operating cash flows used for lease payments	\$	3,168
Operating cash flows used for lease liabilities	\$	859
Operating lease right of use asset obtained in exchange of operating lease liability	\$	22,367

As of December 31, 2020, operating lease assets were \$23.1 million and operating lease liabilities were \$21.6 million. The Company has no finance leases. The maturities of the operating lease liabilities as of December 31, 2020 were as follows (in thousands):

2021	\$	2,505
2022		2,818
2023		3,429
2024		3,525
2025		3,624
2026 and thereafter		13,747
Total undiscounted lease payments		<u>29,648</u>
Less: imputed interest		8,009
Total operating lease liability		<u>21,639</u>
Less: current portion		1,215
Operating lease liability, net of current maturities	\$	<u>20,424</u>

The future minimum lease payments under all non-cancelable operating lease obligations as of December 31, 2019 under ASC 840 were as follows (in thousands):

2020	\$	2,721
2021		3,518
2022		2,942
2023		2,798
2024		2,882
2025 and thereafter		16,328
Total	\$	<u>31,189</u>

In conjunction with the Menlo Park lease agreement, the Company issued a cash-collateralized letter of credit in lieu of security deposit of \$0.2 million. In addition, the Company issued a cash-collateralized letter of credit for \$4.1 million in 2018 for the new office lease in Redwood City, CA. The Company also maintains a letter of credit of \$0.2 million for the benefit of the landlord in connection with the Company's office lease in Boston, MA. All cash amounts are recorded as restricted cash on the consolidated balance sheet as of December 31, 2020 and 2019.

Indemnification Agreements

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never

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incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' liability insurance.

Legal Proceedings

In connection with the Merger, seven lawsuits were filed against the Company, its directors, Former Adicet, and/or Merger Sub. which were either dismissed or settled for of \$0.2 million in the fourth quarter of 2020.

13. Redeemable Convertible Preferred Stock

As of December 31, 2019, redeemable convertible preferred stock consists of the following (in thousands, except per share and share amounts):

	Shares Authorized	Original Issue Price	Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issued Upon Conversion (1)
Series A	37,104,185	\$ 1.20	37,104,185	\$ 35,960	\$ 44,525	4,600,920
Series A-1	629,633	1.20	629,633	447	756	78,074
Series A-2	2,428,688	1.20	2,428,688	1,749	2,914	301,157
Series B	59,200,938	1.40	57,004,415	75,927	80,000	7,068,520
	<u>99,363,444</u>		<u>97,166,921</u>	<u>\$ 114,083</u>	<u>\$ 128,195</u>	<u>12,048,671</u>

(1) Adjusted to reflect the Exchange Ratio.

Following the closing of the Merger, all outstanding shares of the redeemable convertible preferred stock converted into 12,048,671 shares of common stock and the related carrying value was reclassified to common stock and additional paid-in capital. There were no shares of redeemable convertible preferred stock outstanding as of December 31, 2020.

14. Redeemable Convertible Preferred Stock Tranche Liability

The Company determined that the obligations to issue additional shares of Series A redeemable convertible preferred stock at the Milestone Closing and Additional Closing were freestanding instruments that are required to be accounted as a liability initially recorded and subsequently remeasured at fair value until such instruments are exercised or expire. The Milestone Closing liability and Additional Closing liability were initially recorded at \$6.2 million and \$5.0 million, respectively.

The Milestone Closing liability was settled in November 2018 upon the Milestone Closing and the related TRDF liability was settled in March 2019. In July 2019, as part of the Series B redeemable convertible preferred stock purchase agreement the Additional Closing liability and the related TRDF liability were terminated. The Company recorded \$2.0 million gain from the remeasurement of the redeemable convertible preferred stock tranche liability in other income (expense), net in its consolidated statements of operations and comprehensive loss during the years ended December 31, 2019.

The Additional Closing liability was valued using the following assumptions under the option-pricing method:

	Fair Value of Series A Preferred Stock	Term	Interest rate	Volatility
December 31, 2018	\$ 10.48	1.88 years	2.50%	69.80%
July 25, 2019	\$ 7.18	1.31 years	1.95%	69.10%

15. Redeemable Convertible Preferred Stock Warrants and Common Stock Warrants

In connection with Series B redeemable convertible preferred stock financing transactions, the Company issued to its financial advisor warrants to purchase 1,781,387 shares of our Series B redeemable convertible preferred stock at an exercise price of at \$1.4034 per share. These warrants will terminate at the earlier of seven-year anniversary from the issuance date and a liquidation of the company. Additionally, in connection with the entrance into the Loan Agreement, the Company issued

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Pacific Western Bank a warrant to purchase shares of its Series B redeemable convertible preferred stock (see Note 9). These warrants together are referred to as Series B Warrants.

Prior to the Merger, the Company classified the Series B Warrants as a liability on its consolidated balance sheet because the warrants are freestanding financial instruments that may have required the Company to transfer assets upon exercise. The liability associated with each of these warrants was initially recorded at fair value upon the issuance date of each warrant and was subsequently remeasured to fair value as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. Upon the closing of the Merger (see Note 3), pursuant to the Merger Agreement, all of the Series B Warrants converted to warrants for the purchase of the shares of the Company's common stock. The Company assessed the features of the warrants and determined that they qualify for classification as permanent equity upon the closing of the Merger. Accordingly, the Company remeasured the warrants to fair value upon the closing of the Merger, which was \$2.9 million on September 15, 2020. Upon the closing of the Merger, the warrant liability was reclassified to additional paid-in capital. The fair value of the warrants to purchase shares of the Company's common stock was equal to the fair value of the Series B Warrants on the Merger date. Accordingly, no incremental expense was recognized at the Merger date.

The Series B Warrants had a fair value of \$1.9 million as of December 31, 2019. The change in fair value of \$0.8 and \$0.2 million during the years ended December 31, 2020 and 2019, respectively, was recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss.

The redeemable convertible preferred stock warrant liability was valued using the following assumptions under the Black-Scholes option-pricing model:

	September 14, 2020 (Conversion Date)	April 28, 2020 (Issuance Date of PacWest Warrants)	December 31, 2019
Stock price	\$ 16.59	\$ 11.61	\$ 11.32
Expected term (years)	5.86 - 6.62	7.00	6.57 - 6.74
Expected volatility	81.1% - 82.1%	91.17%	82.1% - 93.3%
Risk-free interest rate	0.35% - 0.42%	0.52%	1.53% - 1.93%
Dividend yield	0%	0%	0%

The following table provides a roll forward of outstanding warrants:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Contractual Term (Years)
Outstanding and exercisable warrants to purchase preferred shares as of December 31, 2019	1,781,387	\$ 1.4034	
Issued	128,260		
Impact of converting to warrants for the purchase of common stock and adjusted for the Exchange Ratio and Reverse Stock Split	(1,683,456)		
Outstanding and exercisable warrants to purchase common stock as of December 31, 2020	<u>226,191</u>	\$ 11.3177	5.66

As of December 31, 2020, the Company's outstanding warrants to purchase shares of common stock, including the New PacWest Warrant, consisted of the following:

Issuance Date	Number of Shares of Common Stock Issuable	Exercise Price	Classification	Expiration Date
September 15, 2020	101,610	\$ 11.3177	Equity	July 25, 2026
September 15, 2020	30,924	\$ 11.3177	Equity	August 21, 2026
September 15, 2020	77,312	\$ 11.3177	Equity	September 19, 2026
September 15, 2020	11,044	\$ 11.3177	Equity	September 26, 2026
September 15, 2020	5,301	\$ 11.3177	Equity	April 28, 2027
	<u>226,191</u>			

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As of December 31, 2019, the Company's outstanding warrants to purchase shares of redeemable convertible preferred stock (which converted into warrants to purchase common stock upon close of the Merger) consisted of the following (not adjusted for the Exchange Ratio):

Warrant Name	Issuance Date	Number of Shares of Preferred Stock Issuable	Exercise Price	Exercisable for	Classification	Expiration Date
Series B warrants	July 25, 2019	819,438	\$ 1.4034	Series B	Liability	July 25, 2026
Series B warrants	August 21, 2019	249,394	\$ 1.4034	Series B	Liability	August 21, 2026
Series B warrants	September 19, 2019	623,486	\$ 1.4034	Series B	Liability	September 19, 2026
Series B warrants	September 26, 2019	89,069	\$ 1.4034	Series B	Liability	September 26, 2026
		<u>1,781,387</u>				

16. 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 December 31, 2020 and 2019, no dividends on common stock had been declared by the Board of Directors.

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

	December 31	
	<u>2020</u>	<u>2019</u>
Conversion of redeemable convertible preferred stock (as converted to common stock)	—	12,048,671
Conversion of additional authorized and unissued redeemable convertible preferred stock	—	51,506
Stock options available for future grant	1,739,621	653,136
Stock options issued and outstanding	3,706,945	1,860,646
Redeemable convertible preferred stock warrants issued and outstanding	—	220,890
Common stock warrants issued and outstanding	226,191	—
Total common stock reserved	<u>5,672,757</u>	<u>14,834,849</u>

17. At-the-Market (ATM) Offering

On December 1, 2020, the Company entered into a Sales Agreement (the 2020 Sales Agreement) with Evercore Group L.L.C. and H.C. Wainwright & Co., LLC (collectively, the Agents), pursuant to which the Company may sell, from time to time, at its option, up to an aggregate of \$50.0 million of shares of the Company's common stock, through the Agents, as its sales agents. No sales of Shares have been made under the 2020 Sales Agreement. The ATM offering was terminated in February 2021.

18. Stock-Based Compensation

Summary of Plans

Upon completion of the Merger with resTORbio on September 15, 2020, Former Adicet's 2014 Share Option Plan (the 2014 Plan), Former Adicet's 2015 Stock Incentive Plan (the 2015 Plan), resTORbio's 2017 Stock Incentive Plan (the 2017 Plan), resTORbio's 2018 Stock Incentive Plan (the 2018 Plan) and resTORbio's 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) were assumed by the Company. The Plans are administered by the Board of Directors or, at the discretion of the Board of Directors, by a committee of the Board of Directors. No further shares will be issued from the 2014 Plan or 2017 Plan. The exercise prices, vesting and other restrictions are determined at the discretion of the Board of Directors, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of the stock option may not be greater than ten years. Incentive stock options granted to employees and restricted stock awards granted to employees, officers, members of the Board of Directors, advisors, and consultants of the Company typically vest over four years. Non-statutory options granted to employees, officers, members of the Board of Directors, advisors, and consultants of the Company typically vest over three or four years. Shares that are expired, terminated, surrendered or canceled under the Plans without having been fully exercised will be available for future awards. In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for the grant of awards.

The 2017 Plan and 2018 Plan

In 2017, resTORbio adopted the 2017 Plan. In connection with resTORbio's initial public offering completed in January 2018, the resTORbio Board adopted and resTORbio's stockholders approved the 2018 Plan. The 2018 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2019, by 4% of the outstanding number of shares of resTORbio's common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Board. On January 1, 2021, the number of shares reserved and available for issuance under the 2018 Plan automatically increased by 787,089 shares of Common Stock equal to 4% of the number of shares of Common Stock issued and outstanding on December 31, 2020.

Since the date of effectiveness of the 2018 Plan, resTORbio has not and the Company will not grant any further awards under the 2017 Plan. However, any shares of common stock subject to awards under the 2017 Plan that expire, terminate, or otherwise are surrendered, canceled, forfeited or repurchased without having been fully exercised or resulting in any common stock being issued will become available for issuance under the 2018 Plan.

As of December 31, 2020, the number of shares of common stock available for grant under the 2017 and 2018 Plan is 1,456,492. As of December 31, 2020, an aggregate of 1,317,892 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 \$15.62 per share.

The 2014 Plan and 2015 Plan

At the Effective Time of the Merger, each outstanding and unexercised option to purchase Former Adicet's common stock, whether vested or unvested, pursuant to the 2015 Plan and a subset of options issued pursuant to the 2014 Plan were converted into options to purchase a number of shares of the Company's common stock based on the Exchange Ratio.

As of December 31, 2020, the number of shares of common stock available for grant under the 2014 and 2015 Plan is 283,129. As of December 31, 2020, an aggregate of 1,957,536 shares of common stock were issuable upon the exercise of outstanding stock options under the 2015 plan at a weighted average exercise price of \$7.43 per share and an aggregate of 69,014 shares of common stock were issuable upon the exercise of outstanding stock options under the 2014 Plan at a weighted average exercise price of \$1.27 per share.

Since the date of effectiveness of the Merger, the Company has not and will not grant any further awards under the 2014 Plan.

2018 Employee Stock Purchase Plan

The resTORbio Board adopted and resTORbio's stockholders approved the 2018 ESPP, which became effective on the date immediately preceding the date on which resTORbio's registration statement on Form S-1 became effective. As a result of the Merger, the 2018 ESPP enables eligible employees to purchase shares of the Company's common stock at a discount. Prior to the Merger, the number of shares of common stock originally reserved for issuance under the 2018 ESPP were 39,290 shares. The 2018 ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2019 and increasing each January 1 thereafter through January 1, 2028, by the least of (i) 1% of the outstanding number of shares of

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the Company's common stock on the immediately preceding December 31; (ii) 77,703 shares or (iii) such number of shares as determined by the ESPP administrator. On January 1, 2019, 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 39,290 to 79,369 shares. On January 1, 2020, 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 79,369 to 131,432 shares. No shares have been issued under the 2018 ESPP during the year ended December 31, 2020.

Inducement Grants

As of December 31, 2020, an aggregate of 362,503 shares 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.

Former CEO's Stock Option Modification

In connection with the Merger, the stock options granted to Dr. Singhal were modified (see Note 3), which resulted in acceleration and recognition of the stock compensation expense of \$0.6 million during the quarter ended September 30, 2020. The modification also resulted in incremental stock compensation expense of \$0.1 million that will be recognized through May 7, 2021 as the Company determined that Dr. Singhal will be providing substantial services under the ICSA through that date. The ICSA was terminated in February 2021.

Former CEO's Performance Option

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On July 14, 2020, the Company's Board of Directors confirmed that the conditions for Dr. Singhal's Second Target Milestone Option (as defined in Dr. Singhal's amendment to his employment agreement with the Company, dated October 15, 2019) had been fulfilled as the Company achieved the milestone for the selection of a clinical candidate to the second collaboration target under the Regeneron Agreement. According to Dr. Singhal's employment agreement, Dr. Singhal would be granted an option to purchase 22,574 shares of the Company's common stock related to the achievement of this milestone option. However, as this milestone option was earned during his transition from Chief Executive Officer to an advisory role, only 75% of this option vested. As a result, following the Merger, on September 17, 2020, the Company's Board of Directors granted this option to Dr. Singhal to purchase 16,931 shares of the Company's common stock at an exercise price of \$16.11 per share, (i) one-third of the shares vesting on the first anniversary of May 6, 2019, (ii) one-third of the shares vesting in 12 equal monthly installments following such first anniversary, and (iii) one-third of the shares vesting in accordance with the terms of his Transition Agreement which consisted of 12 months' of accelerated vesting of his unvested options to purchase the Company's common stock upon completion of the Merger. The Company recognized \$0.1 million in stock compensation expense associated with this reward during the year ended December 31, 2020.

Options

A summary of stock option activity is set forth below (in thousands, except share and per share data):

	Number of Shares Available for Grant	Outstanding Awards		Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
		Number of Shares Underlying Outstanding Options	Weighted Average Exercise Price		
Outstanding, January 1, 2018	38,055	963,435	\$ 2.02	9.27	\$ 4,977
Options authorized	837,000				
Options granted	(210,452)	210,452	\$ 2.26		
Options exercised	—	(123,949)	\$ 1.92		
Options forfeited or cancelled	153,399	(153,399)	\$ 2.25		
Outstanding, December 31, 2018	818,002	896,539	\$ 2.04	8.57	\$ 2,436
Options authorized	814,184				
Options granted	(1,124,430)	1,124,430	\$ 5.39		
Options exercised	—	(14,791)	\$ (2.12)		
Options forfeited or cancelled	145,380	(145,532)	\$ 2.17		
Outstanding, December 31, 2019	653,136	1,860,646	\$ 4.05	8.53	\$ 5,812
Assumed as part of the Merger	2,707,144	81,370	\$ 8.39		
Options granted	(1,914,142)	2,276,645	\$ 15.14		
Options exercised	—	(210,752)	\$ 2.18		
Options forfeited or cancelled	293,483	(300,964)	\$ 6.04		
Outstanding, December 31, 2020	1,739,621	3,706,945	\$ 10.90	7.98	\$ 15,126
Shares exercisable December 31, 2020		1,219,904	\$ 4.64	5.11	\$ 11,563
Vested and expected to vest, December 31, 2020		3,706,945	\$ 10.90	7.98	\$ 15,126

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money at December 31, 2020, 2019 and 2018.

The aggregate intrinsic value of stock options exercised during the years ended on December 31, 2020, 2019 and 2018 was \$2.5 million, \$0.1 million and \$0.4 million, respectively.

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The total fair value of options that vested during the years ended December 31, 2020, 2019 and 2018 was \$2.4 million, \$0.9 million and \$1.8 million, respectively. The options granted during the years ended December 31, 2020, 2019 and 2018 had a weighted-average per share grant-date fair value of \$9.96 per share, \$2.98 per share and \$3.95 per share, respectively. As of December 31, 2020, the total unrecognized stock-based compensation expense related to unvested stock options was \$21.6 million, which is expected to be recognized over the remaining weighted-average vesting period of 3.6 years.

Restricted Stock

Activity with respect to restricted stock was as follows:

	Number of Shares Underlying Outstanding Restricted Stock	Weighted Average Grant Date Fair Value
Unvested, January 1, 2018	165,699	\$ 4.19
Vested	(134,516)	\$ 4.19
Unvested, December 31, 2018	31,183	\$ 4.19
Vested	(31,183)	\$ 4.19
Unvested, December 31, 2019	—	\$ —

As of December 31, 2020, there was no unrecognized compensation cost related to restricted stock.

The fair value of restricted stock vested during the years ended December 31, 2020, 2019 and 2018 was \$0, \$0.1 million and \$0.6 million, respectively.

Stock-Based Compensation Associated with Awards to Employees and Non-Employees

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

	Year Ended December 31,		
	2020	2019	2018
Research and development	\$ 1,674	\$ 274	\$ 285
General and administrative	3,589	901	2,194
Total stock-based compensation	\$ 5,263	\$ 1,175	\$ 2,479

The Company estimated the fair value of stock options using the Black Scholes option-pricing model. The fair value of stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of stock options was estimated using the following weighted-average assumptions:

	Year Ended December 31,		
	2020	2019	2018
Expected volatility	72.6%-96.3%	71.5%-86.5%	73.3%-74%
Risk-free interest rate	0.1%-1.7%	1.6%-2.5%	2.7%-2.8%
Dividend yield	0%	0%	0%
Expected term	1.00-6.08 years	5.15-6.08 years	6.02-6.08 years

The assumptions are as follows:

- *Expected volatility.* The expected volatility was determined by examining the historical volatilities for comparable publicly traded companies within the biotechnology and pharmaceutical industry using an average of historical volatilities of the Company's industry peers.
- *Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield with a maturity equal to the expected term of the option in effect at the time of grant.
- *Dividend yield.* The expected dividend is assumed to be zero as dividends have never been paid and there are no current plans to pay dividends on common stock.
- *Expected term.* The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term is calculated using the simplified method which is used when there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under

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this method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.

In addition to the assumptions used in the Black-Scholes option-pricing model, the Company recognizes the actual forfeitures by reducing the employee stock-based compensation expense in the same period the forfeiture occurs.

The Company will continue to use judgment in evaluating the expected volatility, risk-free interest rates, dividend yield and expected term, utilized for stock-based compensation on a prospective basis.

19. 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):

	Year Ended December 31,		
	2020	2019	2018
Numerator:			
Net loss attributable to common stockholders	\$ (36,678)	\$ (28,138)	\$ (9,299)
Denominator:			
Weighted-average shares outstanding	7,319,977	2,148,317	2,049,680
Less: weighted-average unvested restricted shares and shares subject to repurchase	—	(9,344)	(102,704)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	7,319,977	2,138,973	1,946,976
Net loss per share attributable to common stockholders, basic and diluted	\$ (5.01)	\$ (13.15)	\$ (4.78)

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:

	December 31,		
	2020	2019	2018
Redeemable convertible preferred stock (as converted to common stock)	—	12,048,671	4,971,762
Options to purchase common stock	3,706,945	1,860,646	896,539
Redeemable convertible preferred stock warrants	—	220,890	—
Common stock warrants	226,191	—	—
Unvested early exercised common stock options	—	—	27,709
Unvested restricted stock awards	—	—	31,183
Redeemable convertible preferred stock tranche liability and TRDF obligation	—	—	743,317
Total	3,933,136	14,130,207	6,670,510

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20. Income Taxes

The components of the provision for (benefit from) income taxes are as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Current:			
Federal	\$ (2,678)	\$ —	\$ —
State	105	1	(589)
Foreign	—	18	—
Total current	(2,573)	19	(589)
Deferred:			
Federal	(242)	—	—
State	—	—	—
Foreign	—	—	—
Total deferred	(242)	—	—
Provision for (benefit from) income taxes	\$ (2,815)	\$ 19	\$ (589)

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) was enacted in response to the COVID-19 Pandemic. The tax relief measures under the CARES Act for businesses include a five-year net operating loss carryback, suspension of annual deduction limitation of 80% of taxable income from net operating losses generated in a tax year beginning after December 31, 2017, changes in the deductibility of interest, acceleration of alternative minimum tax credit refunds, payroll tax relief, and a technical correction to allow accelerated deductions for qualified improvement property.

The Company recognized income tax benefit of \$2.8 million for the year ended December 31, 2020 due to the net operating loss carryback under the CARES Act which generated a refund of income taxes paid in 2017 and revaluation of IPR&D at year-end. The state tax expense for the year ended December 31, 2020 is due to state minimum and franchise taxes, and true-up of state tax refund.

For the rate table below the (provision for) benefit from income taxes differ from the amount expected by applying the federal statutory rate to the loss before taxes as follows:

	Year Ended December 31,		
	2020	2019	2018
Federal statutory income tax rate	21.0%	21.0%	21.0%
Other permanent differences	(0.5)%	(0.1)%	(0.1)%
State income taxes	6.1%	5.1%	3.8%
Foreign rate differential	0.0%	0.0%	0.2%
Foreign loss	0.0%	(0.2)%	(2.2)%
Federal benefit from NOL carryback	6.7%	0.0%	0.0%
Change in valuation allowance	(25.8)%	(27.7)%	(20.0)%
Change in fair value of redeemable convertible preferred stock tranche liability and TRDF liability	(0.5)%	1.7%	8.7%
Stock-based compensation	0.1%	0.1%	(6.0)%
Benefit from (provision for) income taxes	7.1%	(0.1)%	5.4%

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The tax effects of temporary differences and carryforwards of the deferred tax assets are presented below (in thousands):

	December 31,		
	2020	2019	2018
Deferred Tax Assets:			
Net operating loss carryforwards	\$ 51,796	\$ 12,510	\$ 5,233
Operating lease right-of-use asset liability	5,686	—	—
Deferred revenue	2,857	5,719	5,125
Stock-based compensation	1,750	509	274
Intangible assets	1,195	609	804
Accruals and reserves	654	446	431
Research and development credit carryforwards	26	26	26
Gross deferred tax assets	63,964	19,819	11,893
Less: Valuation allowance	(57,715)	(19,815)	(11,739)
Deferred tax assets, net of valuation allowance	6,249	4	154
Deferred tax liabilities:			
Fixed assets	—	(4)	(154)
Basis Difference IPR&D	(313)	—	—
Operating lease right-of-use asset	(6,061)	—	—
Net deferred tax liability	\$ (125)	\$ —	\$ —

On September 15, 2020 Adicet Bio and resTORbio completed the Merger upon which Adicet Bio became the parent company of the consolidated group. The Merger did not create a step up in basis for tax basis of the asset as it was considered a tax-free merger. The above deferred tax table includes deferred related to resTORbio.

The Company has established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is “more likely than not.” Realization of the future tax benefits is dependent on the Company’s ability to generate sufficient taxable income within the carryforward period. Because of the Company’s recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a valuation allowance.

The valuation allowance increased by \$37.9 million during 2020 and \$8.1 million during 2019.

As of December 31, 2020, the Company had net operating loss carryforwards of \$211.4 million, \$82.2 million and \$16.7 million to reduce future taxable income, if any, for federal, state and foreign income tax purposes, respectively. Of the federal net operating loss carryforwards, \$7.6 million will begin to expire in 2037 if not utilized, and \$203.8 million can be carried forward indefinitely. The state carryforwards will begin to expire in 2035.

The Company also had California research and development credit carryforwards of less than \$0.1 million as of December 31, 2020. The California research credit can be carried forward indefinitely.

Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has 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. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company’s stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed and

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any limitation is known, no liability related to uncertain tax positions is recorded in the consolidated financial statements. The Company does not expect its unrecognized tax benefit balance to change materially over the next 12 months.

The Company files income tax returns in the U.S. federal jurisdiction, California, Massachusetts, New York and Israel. The tax years 2015 to 2020 remains open to U.S. federal and state examination to the extent of the utilization of net operating loss and credit carryovers.

As of December 31, 2020, the Company had unrecognized tax benefits of \$0.8 million related to the transfer of certain intellectual property from its Israeli subsidiary.

A reconciliation of the beginning and ending unrecognized tax benefit amount is as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Balance at the beginning of the year	\$ 797	\$ 797	\$ 866
Adjustment based on tax positions related to prior years	—	—	(69)
Balance at the end of the year	\$ 797	\$ 797	\$ 797

The Company recognizes interest expense and penalties related to the above unrecognized tax benefits within income tax expense (benefit). Management determined that no accrual for interest and penalties was required as of December 31, 2020.

21. Defined Contribution Plan

The Company maintains a defined contribution plan under Section 401(k) of the Internal Revenue Code covering substantially all full-time U.S. employees. Employee contributions are voluntary and are determined on an individual basis subject to the maximum allowable under federal tax regulations. The Company did not make contributions to the 401(k) plan during 2020.

22. Related Party Transaction

As of December 31, 2020, Regeneron owned 883,568 shares of the Company's common stock. As of December 31, 2019, Regeneron owned 7,125,552 shares (not adjusted for the Exchange Ratio) of the Company's redeemable convertible preferred stock. Regeneron became a related party in July 2019 as a result of Series B redeemable convertible preferred stock financing. Upon closing the Merger 7,125,552 shares of the redeemable convertible preferred stock converted into 883,568 shares of the Company's common stock. For the years ended December 31, 2020, 2019 and 2018, the Company recorded revenue of \$17.9 million, \$1.0 million and \$8.2 million, respectively. As of December 31, 2020, the Company recorded no accounts receivable and has deferred revenue of \$14.0 million related to the Regeneron Agreement (See Note 10).

23. Subsequent Events

In February 2021, we completed an underwritten public offering of 10,575,513 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to an additional 1,344,743 shares of common stock at a public offering price of \$13.00 per share. The 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.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
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>
4.1	<u>Description of Securities (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K (File No. 001-38359) filed with the SEC on March 12, 2020).</u>
4.2	<u>Amended and Restated Investors' Rights Agreement, dated as of November 29, 2017, among the Registrant and the other parties thereto (incorporated by reference to Exhibit 4.2 to our Registration Statement on Form S-1 (File No. 333-222373) filed with the SEC on December 29, 2017).</u>
10.1	<u>Escrow Agreement, dated as of September 15, 2020 by and among resTORbio, Inc. and the investors listed on the Schedule of Investors attached thereto. (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 September 16, 2020).</u>
10.2+	<u>Contingent Value Rights Agreement, dated as of September 15, 2020 by and among resTORbio, Inc., Computershare Inc. and Computershare Trust Company, N.A. (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 September 16, 2020).</u>
10.3	<u>Second Amendment to Loan and Security Agreement, dated as of September 14, 2020, by and between Pacific West Bank and Adicet Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 16, 2020).</u>
10.4	<u>Third Amendment to Loan and Security Agreement, dated as of September 15, 2020, by and between Pacific West Bank and Adicet Therapeutics, Inc. (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 16, 2020).</u>
10.5	<u>Form of Warrant to Purchase Common Stock issued to Beech Hill Securities, dated September 15, 2020 (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 16, 2020).</u>
10.6	<u>Warrant to Purchase Common Stock issued to PacWest Bancorp, dated September 15, 2020 (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 16, 2020).</u>
10.7	<u>Unconditional Secured Guaranty, dated September 15, 2020 (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 16, 2020).</u>
10.8	<u>Amendment No. 1 to Loan and Security Agreement, dated as of July 8, 2020, between Adicet Therapeutics, Inc. and Pacific Western Bank (incorporated by reference to Exhibit 10.32 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 16, 2020).</u>
10.9#	<u>First Amendment to the Adicet Bio, Inc. 2018 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.33 to the Registrant's Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 16, 2020).</u>
10.10#	<u>Employment Agreement, dated as of September 15, 2020, by and between the Company and Chen Schor (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 September 18, 2020).</u>

Exhibit Number	Description of Exhibit
10.11#	Employment Agreement, dated as of September 15, 2020, by and between the Company and Carrie Krehlik (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 September 18, 2020).
10.12#	Employment Agreement, dated as of September 15, 2020, by and between the Company and Francesco Galimi (incorporated by reference to Exhibit 10.3 to the Registrant’s Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 18, 2020).
10.13#	Employment Agreement, dated as of September 15, 2020, by and between the Company and Lloyd Klickstein (incorporated by reference to Exhibit 10.4 to the Registrant’s Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 18, 2020).
10.14#	Employment Agreement, dated as of September 15, 2020, by and between the Company and Nick Harvey (incorporated by reference to Exhibit 10.5 to the Registrant’s Current Report on Form 8-K (File No. 001-38359) filed with the SEC on September 18, 2020).
10.15	First Amendment to Lease, dated as of December 30, 2020, between Adicet Therapeutics, Inc. as Tenant, and Westport Office Park, LLC as Landlord (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 January 5, 2021).
10.16	Office Lease Agreement, dated as of January 8, 2018, by and between the Registrant and 500 Boylston and 222 Berkeley Owner (DE) LLC (incorporated by reference to Exhibit 10.15 to the Registrant’s Registration Statement on Form S-1, as amended, (File No. 333-222373) filed with the SEC on January 16, 2018).
10.17	First Amendment to Office Lease, dated as of April 1, 2019, by and between the Registrant and 500 Boylston and 222 Berkeley Owner (DE) LLC (incorporated by reference to Exhibit 10.2 to the Registrant’s Quarterly Report on Form 10-Q (File No. 001-38359) filed with the SEC on May 15, 2019).
10.18	Amendment No. 2 to License Agreement, dated August 20, 2019, by and between the Registrant and Novartis International Pharmaceutical Ltd. (incorporated by reference to Exhibit 10.1 to the Registrant’s Quarterly Report on Form 10-Q (File No. 001-38359) filed with the SEC on November 5, 2019).
10.19	Stock Purchase Agreement, dated February 12, 2021, by and among the Registrant and the Investors named therein (incorporated by reference to Exhibit 10.1 to the Registrant’s Registration Statement on Form 8-K, as amended (File No. 001-38359) filed with the SEC on February 16, 2021).
10.20*	Registration Rights Agreement, dated February 12, 2021, by and among the Registrant and the Investors named therein.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of KPMG LLP, independent registered public accounting firm.
23.2*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial 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.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
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.

+ Confidential treatment granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

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

** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or 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 Section 13 or 15(d) 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: March 11, 2021

By: /s/ Chen Schor

Chen Schor

President, Chief Executive Officer and Director

(Principal Executive Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Chen Schor and Nick Harvey, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1934, this Annual Report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Chen Schor</u> Chen Schor	President, Chief Executive Officer and Director (principal executive officer)	March 11, 2021
<u>/s/ Nick Harvey</u> Nick Harvey	Chief Financial Officer (principal financial officer and principal accounting officer)	March 11, 2021
<u>/s/ Jeffrey Chodakewitz</u> Jeffrey Chodakewitz	Director	March 11, 2021
<u>/s/ Steve Dubin</u> Steve Dubin	Director	March 11, 2021
<u>/s/ Carl L. Gordon</u> Carl L. Gordon, Ph.D	Director	March 11, 2021
<u>/s/ Aya Jakobovits</u> Aya Jakobovits, Ph.D.	Director	March 11, 2021
<u>/s/ Bastiano Sanna</u> Bastiano Sanna, Ph.D	Director	March 11, 2021
<u>/s/ Andrew Sinclair</u> Andrew Sinclair	Director	March 11, 2021

REGISTRATION RIGHTS AGREEMENT

This Registration Rights Agreement (this “*Agreement*”) is dated as of February 12, 2021, by and among Adicet Bio, Inc., a Delaware corporation (the “*Company*”), and the several purchasers signatory hereto (each, including its successors and assigns, a “*Purchaser*” and collectively, the “*Purchasers*”).

This Agreement is made pursuant to the Stock Purchase Agreement, dated as of the date hereof, between the Company and each Purchaser (the “*Purchase Agreement*”).

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and each of the Purchasers agree as follows:

1. **Definitions.** Capitalized terms used and not otherwise defined herein that are defined in the Purchase Agreement shall have the meanings given such terms in the Purchase Agreement. As used in this Agreement, the following terms shall have the following meanings:

“*Advice*” has the meaning set forth in Section 6(d).

“*Affiliate*” means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 of the Securities Act of 1933, as amended.

“*Agreement*” has the meaning set forth in the Preamble.

“*Business Day*” means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

“*Closing*” means the Initial Closing (as such term is defined in the Purchase Agreement).

“*Closing Date*” has the meaning set forth in the Purchase Agreement.

“*Commission*” means the United States Securities and Exchange Commission.

“*Common Stock*” means the Company’s common stock, par value \$0.0001 per share, and stock of any other class of securities into which such securities may hereafter be reclassified or changed.

“*Company*” has the meaning set forth in the Preamble.

“*Effective Date*” means the date that the Registration Statement filed pursuant to Section 2(a) is first declared effective by the Commission.

“*Effectiveness Deadline*” means, with respect to the Initial Registration Statement or the New Registration Statement, the thirtieth (30th) calendar day following the Filing Deadline (or, in the event the Commission reviews and has written comments to the Initial Registration Statement or the New Registration Statement, the sixtieth (60th) calendar day following the Filing Deadline); *provided, however*, that if the Company is notified by the Commission (orally or in writing, whichever is earlier) that the Initial Registration Statement or the New Registration Statement will not be reviewed or is no longer subject to further review and comments, the Effectiveness Deadline as to such Registration Statement shall be the

fifth (5th) Trading Day following the date on which the Company is so notified if such date precedes the dates otherwise required above; *provided, further*, that if the Effectiveness Deadline falls on a Saturday, Sunday or other day that the Commission is closed for business, the Effectiveness Deadline shall be extended to the next Business Day on which the Commission is open for business.

“*Effectiveness Period*” has the meaning set forth in Section 2(b).

“*Exchange Act*” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“*Filing Deadline*” means, with respect to the Initial Registration Statement required to be filed pursuant to Section 2(a), the ninetieth (90th) calendar day following the Closing Date, *provided, however*, that if the Filing Deadline falls on a Saturday, Sunday or other day that the Commission is closed for business, the Filing Deadline shall be extended to the next business day on which the Commission is open for business.

“*Holder*” or “*Holder*s” means the holder or holders, as the case may be, from time to time of Registrable Securities.

“*Indemnified Party*” has the meaning set forth in Section 5(c).

“*Indemnifying Party*” has the meaning set forth in Section 5(c).

“*Initial Registration Statement*” means the initial Registration Statement filed pursuant to Section 2(a) of this Agreement.

“*Losses*” has the meaning set forth in Section 5(a).

“*New Registration Statement*” has the meaning set forth in Section 2(a).

“*Person*” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“*Principal Market*” means the Trading Market on which the Common Stock are primarily listed on and quoted for trading, which, as of the Closing Date, shall be the Nasdaq Global Market.

“*Proceeding*” means an action, claim, suit, investigation or proceeding (including, without limitation, an investigation or partial proceeding, such as a deposition), whether commenced or threatened.

“*Prospectus*” means the prospectus included in a Registration Statement (including, without limitation, a prospectus that includes any information previously omitted from a prospectus filed as part of an effective registration statement in reliance upon Rule 430B promulgated under the Securities Act), as amended or supplemented by any prospectus supplement, with respect to the terms of the offering of any portion of the Registrable Securities covered by a Registration Statement, and all other amendments and supplements to the Prospectus, including post-effective amendments, and all material incorporated by reference or deemed to be incorporated by reference in such Prospectus.

“*Purchase Agreement*” has the meaning set forth in the Recitals.

“*Purchaser*” or “*Purchasers*” has the meaning set forth in the Preamble.

“*Registrable Securities*” means all of (i) the Shares and (ii) any securities issued or issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect to the foregoing, *provided*, that the Holder has completed and delivered to the Company a Selling Shareholder Questionnaire; and *provided, further*, that with respect to a particular Holder, such Holder’s Shares shall cease to be Registrable Securities upon the earliest to occur of the following: (A) a sale pursuant to a Registration Statement or Rule 144 under the Securities Act (in which case, only such security sold by the Holder shall cease to be a Registrable Security); (B) becoming eligible for resale by the Holder under Rule 144 without the requirement for the Company to be in compliance with the current public information required thereunder and without volume or manner-of-sale restrictions, pursuant to a written opinion letter of counsel for the Company to such effect, addressed, delivered and reasonably acceptable to the Transfer Agent; or (c) the expiration of sixty (60) months from the Closing Date.

“*Registration Statements*” means any one or more registration statements of the Company filed under the Securities Act that covers the resale of any of the Registrable Securities pursuant to the provisions of this Agreement (including without limitation the Initial Registration Statement, the New Registration Statement and any Remainder Registration Statements), amendments and supplements to such Registration Statements, including post-effective amendments, all exhibits and all material incorporated by reference or deemed to be incorporated by reference in such Registration Statements.

“*Remainder Registration Statement*” has the meaning set forth in [Section 2\(a\)](#).

“*Rule 144*” means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

“*Rule 415*” means Rule 415 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

“*Rule 424*” means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

“*SEC Guidance*” means (i) any publicly-available written or oral guidance, comments, requirements or requests of the Commission staff; provided, that any such oral guidance, comments, requirements or requests are reduced to writing by the Commission and (ii) the Securities Act.

“*Securities Act*” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“*Selling Shareholder Questionnaire*” means a questionnaire in the form attached as [Annex B](#) hereto, or such other form of questionnaire as may reasonably be adopted by the Company from time to time.

“*Shares*” means the shares of Common Stock purchased by the Purchasers and issued by the Company pursuant to the Purchase Agreement.

“*Trading Day*” means a day on which the principal Trading Market is open for business.

“*Trading Market*” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital

Market, the Nasdaq Global Market, the Nasdaq Global Select Market, or the New York Stock Exchange (or any successors to any of the foregoing).

2. Registration.

(a) On or prior to the Filing Deadline, the Company shall prepare and file with the Commission a Registration Statement covering the resale of all of the Registrable Securities not then registered on an existing and effective Registration Statement for an offering to be made on a continuous basis pursuant to Rule 415 or, if Rule 415 is not available for offers and sales of the Registrable Securities, by such other means of distribution of Registrable Securities as the Holders may reasonably specify (the “*Initial Registration Statement*”). The Initial Registration Statement shall be on Form S-3 (except if the Company is then ineligible to register for resale the Registrable Securities on Form S-3, in which case such registration shall be on such other form available to register for resale the Registrable Securities as a secondary offering) subject to the provisions of Section 2(d) and shall contain (except if otherwise required pursuant to written comments received from the Commission upon a review of such Registration Statement) the “Plan of Distribution” section substantially in the form attached hereto as Annex A (which may be modified to respond to comments, if any, provided by the Commission). Notwithstanding the registration obligations set forth in this Section 2, in the event the Commission informs the Company that all of the Registrable Securities cannot, as a result of the application of Rule 415, be registered for resale as a secondary offering on a single registration statement, the Company agrees to promptly (i) inform each of the Holders thereof and use its commercially reasonable efforts to file amendments to the Initial Registration Statement as required by the Commission and/or (ii) withdraw the Initial Registration Statement and file a new registration statement (a “*New Registration Statement*”), in either case covering the maximum number of Registrable Securities permitted to be registered by the Commission, on Form S-3 or, if the Company is ineligible to register the Registrable Securities on Form S-3, such other form available to register for resale the Registrable Securities as a secondary offering; *provided, however*, that prior to filing such amendment or New Registration Statement, the Company shall be obligated to use its commercially reasonable efforts to advocate with the Commission for the registration of all of the Registrable Securities in accordance with the SEC Guidance, including without limitation, the Securities Act Rules Compliance and Disclosure Interpretations Question 612.09. Notwithstanding any other provision of this Agreement, if any SEC Guidance sets forth a limitation of the number of Registrable Securities permitted to be registered on a particular Registration Statement as a secondary offering (and notwithstanding that the Company used diligent efforts to advocate with the Commission for the registration of all or a greater number of Registrable Securities), unless otherwise directed in writing by a Holder as to its Registrable Securities, the number of Registrable Securities to be registered on such Registration Statement will first be reduced by Registrable Securities not acquired pursuant to the Purchase Agreement (whether pursuant to registration rights or otherwise), and second by Registrable Securities represented by Shares (applied, in the case that some Shares may be registered, to the Holders on a pro rata basis based on the total number of unregistered Shares held by such Holders, subject to a determination by the Commission that certain Holders must be reduced first based on the number of Shares held by such Holders). In the event the Company amends the Initial Registration Statement or files a New Registration Statement, as the case may be, under clauses (i) or (ii) above, the Company will use its commercially reasonable efforts to file with the Commission, as promptly as allowed by Commission or SEC Guidance provided to the Company or to registrants of securities in general, one or more registration statements on Form S-3 or such other form available to register for resale those Registrable Securities that were not registered for resale on the Initial Registration Statement, as amended, or the New Registration Statement (the “*Remainder Registration Statements*”).

(b) The Company shall use its commercially reasonable efforts to cause each Registration Statement to be declared effective by the Commission as soon as practicable and, with respect to the Initial Registration Statement or the New Registration Statement, as applicable, no later than the

Effectiveness Deadline (including filing with the Commission a request for acceleration of effectiveness in accordance with Rule 461 promulgated under the Securities Act), and shall use its commercially reasonable efforts to keep each Registration Statement continuously effective under the Securities Act until the earlier of (i) such time as all of the Registrable Securities covered by such Registration Statement have been publicly sold by the Holders; (ii) the date that all Registrable Securities covered by such Registration Statement may be sold without volume or manner-of-sale restrictions pursuant to Rule 144, without the requirement for the Company to be in compliance with the current public information requirement under Rule 144 as determined by counsel to the Company pursuant to a written opinion letter to such effect, addressed and reasonably acceptable to the Company's transfer agent or (iii) the expiration of sixty (60) months from the Closing Date (the "*Effectiveness Period*"). The Company shall request effectiveness of a Registration Statement as of 4:00 P.M. New York City time on a Trading Day. The Company shall promptly notify the Holders via e-mail of the effectiveness of a Registration Statement or any post-effective amendment thereto on the same Trading Day that the Company telephonically confirms effectiveness with the Commission, which date of confirmation shall initially be the date requested for effectiveness of such Registration Statement. The Company shall, by 9:30 A.M. New York City time on the first Trading Day after the Effective Date, file a final Prospectus with the Commission, as required by Rule 424(b) and shall provide the Holders with copies of the final Prospectus to be used in connection with the sale or other disposition of the securities covered thereby. The Company shall promptly inform each Holder in writing if, at any time during the Effectiveness Period, the Company does not satisfy the conditions specified in Rule 172 and, as a result thereof, the Holder is required to deliver a Prospectus in connection with any disposition of Registrable Securities.

(c) Each Holder agrees to furnish to the Company a completed Selling Shareholder Questionnaire not more than five (5) Trading Days following the date of this Agreement. At least ten (10) Trading Days prior to the first anticipated filing date of a Registration Statement for any registration under this Agreement, the Company will notify each Holder of the information the Company requires from that Holder other than the information contained in the Selling Shareholder Questionnaire, if any, which shall be completed and delivered to the Company promptly upon request and, in any event, within three (3) Trading Days prior to the applicable anticipated filing date. Each Holder further agrees that it shall not be entitled to be named as a selling securityholder in the Registration Statement or use the Prospectus for offers and resales of Registrable Securities at any time, unless such Holder has returned to the Company a completed and signed Selling Shareholder Questionnaire and a response to any reasonable requests for further information as described in the previous sentence. If a Holder of Registrable Securities returns a Selling Shareholder Questionnaire or a request for further information, in either case, after its respective deadline, the Company shall use its commercially reasonable efforts to take such actions as are required to name such Holder as a selling security holder in the Registration Statement or any pre-effective or post-effective amendment thereto and to include (to the extent not theretofore included) in the Registration Statement the Registrable Securities identified in such late Selling Shareholder Questionnaire or request for further information. Each Holder acknowledges and agrees that the information in the Selling Shareholder Questionnaire or request for further information as described in this Section 2(c) will be used by the Company in the preparation of the Registration Statement and hereby consents to the inclusion of such information in the Registration Statement.

(d) In the event that Form S-3 is not available for the registration of the resale of Registrable Securities hereunder, the Company shall (i) register the resale of the Registrable Securities on another appropriate form reasonably acceptable to the Holders and (ii) undertake to register the Registrable Securities on Form S-3 promptly after such form is available, *provided* that the Company shall maintain the effectiveness of the Registration Statement then in effect until such time as a Registration Statement on Form S-3 covering the Registrable Securities has been declared effective by the Commission.

3. Registration Procedures

In connection with the Company's registration obligations hereunder, the Company shall:

(a) Not less than five (5) Trading Days prior to the filing of each Registration Statement and not less than one (1) Trading Day prior to the filing of any related Prospectus or any amendment or supplement thereto (except for Annual Reports on Form 10-K, and Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and any similar or successor reports), (i) furnish to each Holder copies of such Registration Statement, Prospectus or amendment or supplement thereto, as proposed to be filed, which documents will be subject to the review of such Holder (it being acknowledged and agreed that if a Holder does not object to or comment on the aforementioned documents within such five (5) Trading Day or one (1) Trading Day period, as the case may be, then the Holder shall be deemed to have consented to and approved the use of such documents) and (ii) use commercially reasonable efforts to cause its officers and directors, counsel and independent registered public accountants to respond to such inquiries as shall be necessary, in the reasonable opinion of respective counsel to each Holder, to conduct a reasonable investigation within the meaning of the Securities Act. The Company shall not file any Registration Statement or amendment or supplement thereto in a form to which a Holder reasonably objects in good faith, provided that, the Company is notified of such objection in writing within the five (5) Trading Day or one (1) Trading Day period described above, as applicable.

(b) (i) Prepare and file with the Commission such amendments (including post-effective amendments) and supplements, to each Registration Statement and the Prospectus used in connection therewith as may be necessary to keep such Registration Statement continuously effective as to the applicable Registrable Securities for its Effectiveness Period; (ii) cause the related Prospectus to be amended or supplemented by any required Prospectus supplement (subject to the terms of this Agreement), and, as so supplemented or amended, to be filed pursuant to Rule 424; (iii) respond as promptly as reasonably practicable to any comments received from the Commission with respect to each Registration Statement or any amendment thereto and, as promptly as reasonably possible, provide the Holders true and complete copies of all correspondence from and to the Commission relating to such Registration Statement that pertains to the Holders as "Selling Stockholders" but not any comments that would result in the disclosure to the Holders of material and non-public information concerning the Company; and (iv) comply with the provisions of the Securities Act and the Exchange Act with respect to the disposition of all Registrable Securities covered by a Registration Statement until such time as all of such Registrable Securities shall have been disposed of (subject to the terms of this Agreement) in accordance with the intended methods of disposition by the Holders thereof as set forth in such Registration Statement as so amended or in such Prospectus as so supplemented; *provided, however*, that each Purchaser shall be responsible for the delivery of the Prospectus to the Persons to whom such Purchaser sells any of the Shares (including in accordance with Rule 172 under the Securities Act), and each Purchaser agrees to dispose of Registrable Securities in compliance with the "Plan of Distribution" described in the Registration Statement and otherwise in compliance with applicable federal and state securities laws. In the case of amendments and supplements to a Registration Statement which are required to be filed pursuant to this Agreement (including pursuant to this Section 3(b)) by reason of the Company filing a report on Form 10-K, Form 10-Q or Form 8-K or any analogous report under the Exchange Act, the Company shall have incorporated such report by reference into such Registration Statement, if applicable, or shall file such amendments or supplements with the Commission on the same day on which the Exchange Act report which created the requirement for the Company to amend or supplement such Registration Statement was filed.

(c) Notify the Holders (which notice shall, pursuant to clauses (iii) through (vi) hereof, be accompanied by an instruction to suspend the use of the Prospectus until the requisite changes have been made) as promptly as reasonably practicable (and, in the case of (i)(A) below, not less than one (1) Trading Day prior to such filing) and (if requested by any such Person) confirm such notice in writing no later than

one (1) Trading Day following the day: (i)(A) when a Prospectus or any Prospectus supplement or post-effective amendment to a Registration Statement is proposed to be filed; (B) when the Commission notifies the Company whether there will be a “review” of such Registration Statement and whenever the Commission comments in writing on any Registration Statement (in which case the Company shall provide to each of the Holders true and complete copies of all comments that pertain to the Holders as a “Selling Stockholder” or to the “Plan of Distribution” and all written responses thereto, but not information that the Company believes would constitute material and non-public information); and (C) with respect to each Registration Statement or any post-effective amendment, when the same has become effective; (ii) of any request by the Commission or any other Federal or state governmental authority for amendments or supplements to a Registration Statement or Prospectus or for additional information that pertains to the Holders as “Selling Stockholders” or the “Plan of Distribution”; (iii) of the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of a Registration Statement covering any or all of the Registrable Securities or the initiation of any Proceedings for that purpose; (iv) of the receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Registrable Securities for sale in any jurisdiction, or the initiation or threatening of any Proceeding for such purpose; (v) of the occurrence of any event or passage of time that makes the financial statements included or incorporated by reference in a Registration Statement ineligible for inclusion or incorporation by reference therein or any statement made in such Registration Statement or Prospectus or any document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires any revisions to such Registration Statement, Prospectus or other documents so that, in the case of such Registration Statement or the Prospectus, as the case may be, it will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus, form of prospectus or supplement thereto, in light of the circumstances under which they were made), not misleading and (vi) of the occurrence or existence of any pending corporate development with respect to the Company that the Company reasonably believes may be material and that, in the reasonable determination of the Company, makes it not in the best interest of the Company to allow continued availability of a Registration Statement or Prospectus, *provided* that, any and all such information shall remain confidential to each Holder until such information otherwise becomes public, unless disclosure by a Holder is required by law; and *provided, further*, that notwithstanding each Holder’s agreement to keep such information confidential, each such Holder makes no acknowledgement that any such information is material, non-public information.

(d) Use commercially reasonable efforts to avoid the issuance of, or, if issued, obtain the withdrawal of (i) any order suspending the effectiveness of a Registration Statement, or (ii) any suspension of the qualification (or exemption from qualification) of any of the Registrable Securities for sale in any jurisdiction, as soon as practicable.

(e) If requested by a Holder, furnish to such Holder, without charge, at least one conformed copy of each Registration Statement and each amendment thereto and all exhibits to the extent requested by such Person (including those previously furnished or incorporated by reference) promptly after the filing of such documents with the Commission; *provided*, that the Company shall have no obligation to provide any document pursuant to this clause that is available on the Commission’s EDGAR system.

(f) Prior to any resale of Registrable Securities by a Holder, use its commercially reasonable efforts to register or qualify or cooperate with the selling Holders in connection with the registration or qualification (or exemption from the registration or qualification) of such Registrable Securities for the resale by the Holder under the securities or Blue Sky laws of such jurisdictions within the United States as any Holder reasonably requests in writing, to keep each registration or qualification (or exemption therefrom) effective during the Effectiveness Period and to do any and all other acts or things

reasonably necessary to enable the disposition in such jurisdictions of the Registrable Securities covered by each Registration Statement; *provided*, that the Company shall not be required to qualify generally to do business in any jurisdiction where it is not then so qualified, subject the Company to any material tax in any such jurisdiction where it is not then so subject or file a general consent to service of process in any such jurisdiction.

(g) Cooperate with such Holder to facilitate the timely preparation and delivery of certificates or book entry statements, as applicable, representing Registrable Securities to be delivered to a transferee pursuant to the Registration Statement, which certificates or statements shall be free, to the extent permitted by the Purchase Agreement and under law, of all restrictive legends, including providing an opinion of Company counsel if required by the Company's transfer agent, and to enable such Registrable Securities to be in such denominations and registered in such names as any such Holders may reasonably request.

(h) Following the occurrence of any event contemplated by Section 3(c), as promptly as reasonably practicable (taking into account the Company's good faith assessment of any adverse consequences to the Company and its shareholders of the premature disclosure of such event), prepare a supplement or amendment, including a post-effective amendment, to the affected Registration Statements or a supplement to the related Prospectus or any document incorporated or deemed to be incorporated therein by reference, and file any other required document so that, as thereafter delivered, no Registration Statement nor any Prospectus will contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus, form of prospectus or supplement thereto, in light of the circumstances under which they were made), not misleading. If the Company notifies the Holders in accordance with clauses (iii) through (vi) of Section 3(c) above to suspend the use of any Prospectus until the requisite changes to such Prospectus have been made, then the Holders shall suspend use of such Prospectus. The Company will use its commercially reasonable efforts to ensure that the use of the Prospectus may be resumed as promptly as is practicable. The Company shall be entitled to exercise its right under this Section 3(h) to suspend the availability of a Registration Statement and Prospectus. For the avoidance of doubt, any period of time for which the availability of a Registration Statement and Prospectus are suspended pursuant to Section 2(c) shall be disregarded when determining the time period allotted under this Section 3(h).

(i) The Company may require each selling Holder to furnish to the Company a certified statement as to (i) the number of shares of Common Stock beneficially owned by such Holder and any Affiliate thereof, (ii) any Financial Industry Regulatory Authority ("FINRA") affiliations, (iii) any natural persons who have the power to vote or dispose of the Common Stock and (iv) any other information as may be requested by the Commission, FINRA or any state securities commission.

(j) The Company shall cooperate with any registered broker through which a Holder proposes to resell its Registrable Securities in effecting a filing with FINRA pursuant to FINRA Rule 5110 as requested by any such Holder and the Company shall pay the filing fee required for the first such filing within two (2) Business Days of the request therefor.

4. Registration Expenses. All fees and expenses incident to the Company's performance of or compliance with its obligations under this Agreement (excluding any underwriting discounts and selling commissions and all legal fees and expenses of legal counsel for any Holder) shall be borne by the Company whether or not any Registrable Securities are sold pursuant to a Registration Statement. The fees and expenses referred to in the foregoing sentence shall include, without limitation, (i) all registration and filing fees (including, without limitation, fees and expenses (A) with respect to filings required to be made with any Trading Market on which the Common Stock are then listed for trading, (B) with respect to compliance with applicable state securities or Blue Sky laws (including, without limitation, fees and disbursements of

counsel for the Company in connection with Blue Sky qualifications or exemptions of the Registrable Securities and determination of the eligibility of the Registrable Securities for investment under the laws of such jurisdictions as requested by the Holders) and (C) if not previously paid by the Company in connection with Section 3(j) above, with respect to any filing that may be required to be made by any broker through which a Holder intends to make sales of Registrable Securities with FINRA pursuant to the FINRA Rule 5110, so long as the broker is receiving no more than a customary brokerage commission in connection with such sale), (ii) printing expenses (including, without limitation, expenses of printing certificates for Registrable Securities and of printing prospectuses if the printing of prospectuses is reasonably requested by the Holders of a majority of the Registrable Securities included in the Registration Statement), (iii) messenger, telephone and delivery expenses, (iv) fees and disbursements of counsel for the Company, (v) Securities Act liability insurance, if the Company so desires such insurance, and (vi) fees and expenses of all other Persons retained by the Company in connection with the consummation of the transactions contemplated by this Agreement. In addition, the Company shall be responsible for all of its internal expenses incurred in connection with the consummation of the transactions contemplated by this Agreement (including, without limitation, all salaries and expenses of its officers and employees performing legal or accounting duties), the expense of any annual audit and the fees and expenses incurred in connection with the listing of the Registrable Securities on any securities exchange as required hereunder. In no event shall the Company be responsible for any underwriting, broker or similar fees or commissions of any Holder or, except to the extent provided for in the Transaction Documents, any legal fees or other costs of the Holders.

5. Indemnification.

(a) Indemnification by the Company. The Company shall, notwithstanding any termination of this Agreement, indemnify, defend and hold harmless each Holder, the officers, directors, agents, partners, members, managers, stockholders, Affiliates and employees of each of them, each Person who controls any such Holder (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) and the officers, directors, partners, members, managers, stockholders, agents and employees of each such controlling Person, to the fullest extent permitted by applicable law, from and against any and all losses, claims, damages, liabilities, costs (including, without limitation, reasonable costs of preparation and investigation and reasonable attorneys' fees) and expenses (collectively, "Losses"), as incurred, that arise out of or are based upon (i) any untrue or alleged untrue statement of a material fact contained in any Registration Statement, any Prospectus or any form of prospectus or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus or form of prospectus or supplement thereto, in light of the circumstances under which they were made) not misleading, or (ii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act or any state securities law or any rule or regulation thereunder, in connection with the performance of its obligations under this Agreement, except to the extent, but only to the extent, that (A) such untrue statements, alleged untrue statements, omissions or alleged omissions are based solely upon information regarding such Holder furnished in writing to the Company by such Holder expressly for use therein, or to the extent that such information relates to such Holder or such Holder's proposed method of distribution of Registrable Securities and was reviewed and approved in writing by such Holder expressly for use in the Registration Statement, such Prospectus or such form of Prospectus or in any amendment or supplement thereto (it being understood that each Holder has approved Annex A hereto for this purpose) or (B) in the case of an occurrence of an event of the type specified in Section 3(c)(iii)-(vi), related to the use by a Holder of an outdated or defective Prospectus after the Company has notified such Holder in writing that the Prospectus is outdated or defective and prior to the receipt by such Holder of the Advice contemplated and defined in Section 6(d) below, to the extent that following the receipt of the Advice the misstatement or omission giving rise to such Loss would have been corrected or (C) to the extent that any such Losses arise out of the Purchaser's (or any other indemnified Person's) failure to send or give a copy of the Prospectus or supplement (as then amended or supplemented), if

required, pursuant to Rule 172 under the Securities Act (or any successor rule) to the Persons asserting an untrue statement or alleged untrue statement or alleged untrue statement or omission or alleged omission at or prior to the written confirmation of the sale of Registrable Securities to such Person if such statement or omission was corrected in such Prospectus or supplement. The Company shall notify the Holders promptly of the institution, threat or assertion of any Proceeding arising from or in connection with the transactions contemplated by this Agreement of which the Company is aware. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of an Indemnified Party (as defined in Section 5(c)) and shall survive the transfer of the Registrable Securities by the Holders.

(b) Indemnification by Holders. Each Holder shall, severally and not jointly, indemnify and hold harmless the Company, its directors, officers, agents and employees, each Person who controls the Company (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, agents or employees of such controlling Persons, to the fullest extent permitted by applicable law, from and against all Losses, as incurred, arising out of or are based solely upon any untrue or alleged untrue statement of a material fact contained in any Registration Statement, any Prospectus, or any form of prospectus, or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus, or any form of prospectus or supplement thereto, in light of the circumstances under which they were made) not misleading (i) to the extent that such untrue statements or omissions are based solely upon information regarding such Holder furnished in writing to the Company by such Holder expressly for use therein or (ii) to the extent that such information relates to such Holder or such Holder's proposed method of distribution of Registrable Securities and was reviewed and approved in writing by such Holder expressly for use in a Registration Statement (it being understood that the Holder has approved Annex A hereto for this purpose), such Prospectus or such form of Prospectus or in any amendment or supplement thereto or (iii) in the case of an occurrence of an event of the type specified in Section 3(c)(iii)-(vi), to the extent related to the use by such Holder of an outdated or defective Prospectus after the Company has notified such Holder in writing that the Prospectus is outdated or defective and prior to the receipt by such Holder of the Advice contemplated in Section 6(d). In no event shall the liability of any selling Holder hereunder be greater in amount than the dollar amount of the net proceeds received by such Holder upon the sale of the Registrable Securities giving rise to such indemnification obligation.

(c) Conduct of Indemnification Proceedings. If any Proceeding shall be brought or asserted against any Person entitled to indemnity hereunder (an "*Indemnified Party*"), such Indemnified Party shall promptly notify the Person from whom indemnity is sought (the "*Indemnifying Party*") in writing, and the Indemnifying Party shall have the right to assume the defense thereof, including the employment of counsel reasonably satisfactory to the Indemnified Party and the payment of all reasonable fees and expenses incurred in connection with defense thereof; *provided*, that the failure of any Indemnified Party to give such notice shall not relieve the Indemnifying Party of its obligations or liabilities pursuant to this Agreement, except (and only) to the extent that it shall be finally determined by a court of competent jurisdiction (which determination is not subject to appeal or further review) that such failure shall have materially and adversely prejudiced the Indemnifying Party.

An Indemnified Party shall have the right to employ separate counsel in any such Proceeding and to participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Indemnified Party or Parties unless: (1) the Indemnifying Party has agreed in writing to pay such fees and expenses; (2) the Indemnifying Party shall have failed promptly to assume the defense of such Proceeding and to employ counsel reasonably satisfactory to such Indemnified Party in any such Proceeding; or (3) the named parties to any such Proceeding (including any impleaded parties) include both such Indemnified Party and the Indemnifying Party, and such Indemnified Party shall have been advised by counsel that a conflict of interest exists if the same counsel were to represent such Indemnified Party

and the Indemnifying Party (in which case, if such Indemnified Party notifies the Indemnifying Party in writing that it elects to employ separate counsel at the expense of the Indemnifying Party, the Indemnifying Party shall not have the right to assume the defense thereof and such counsel shall be at the expense of the Indemnifying Party); *provided*, that the Indemnifying Party shall not be liable for the fees and expenses of more than one separate firm of attorneys at any time for all Indemnified Parties. The Indemnifying Party shall not be liable for any settlement of any such Proceeding effected without its written consent, which consent shall not be unreasonably withheld, delayed or conditioned. No Indemnifying Party shall, without the prior written consent of the Indemnified Party, effect any settlement of any pending Proceeding in respect of which any Indemnified Party is a party, unless such settlement includes an unconditional release of such Indemnified Party from all liability on claims that are the subject matter of such Proceeding.

Subject to the terms of this Agreement, all fees and expenses of the Indemnified Party (including reasonable fees and expenses to the extent incurred in connection with investigating or preparing to defend such Proceeding in a manner not inconsistent with this Section 5) shall be paid to the Indemnified Party, as incurred, within twenty (20) Trading Days of written notice thereof to the Indemnifying Party; *provided*, that the Indemnified Party shall promptly reimburse the Indemnifying Party for that portion of such fees and expenses applicable to such actions for which such Indemnified Party is finally judicially determined to not be entitled to indemnification hereunder). The failure to deliver written notice to the Indemnifying Party within a reasonable time of the commencement of any such action shall not relieve such Indemnifying Party of any liability to the Indemnified Party under this Section 5, except to the extent that the Indemnifying Party is materially and adversely prejudiced in its ability to defend such action.

(d) Contribution. If a claim for indemnification under Section 5(a) or 5(b) is unavailable to an Indemnified Party or insufficient to hold an Indemnified Party harmless for any Losses, then each Indemnifying Party, in lieu of indemnifying such Indemnified Party, shall contribute to the amount paid or payable by such Indemnified Party as a result of such Losses, in such proportion as is appropriate to reflect the relative fault of the Indemnifying Party and Indemnified Party in connection with the actions, statements or omissions that resulted in such Losses as well as any other relevant equitable considerations. The relative fault of such Indemnifying Party and Indemnified Party shall be determined by reference to, among other things, whether any action in question, including any untrue or alleged untrue statement of a material fact or omission or alleged omission of a material fact, has been taken or made by, or relates to information supplied by, such Indemnifying Party or Indemnified Party, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such action, statement or omission. The amount paid or payable by a party as a result of any Losses shall be deemed to include, subject to the limitations set forth in this Agreement, any reasonable attorneys' or other reasonable fees or expenses incurred by such party in connection with any Proceeding to the extent such party would have been indemnified for such fees or expenses if the indemnification provided for in this Section 5 was available to such party in accordance with its terms.

The parties hereto agree that it would not be just and equitable if contribution pursuant to this Section 5(d) were determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to in the immediately preceding paragraph. Notwithstanding the provisions of this Section 5(d), (A) no Holder shall be required to contribute, in the aggregate, any amount in excess of the amount by which the net proceeds actually received by such Holder from the sale of the Registrable Securities subject to the Proceeding exceeds the amount of any damages that such Holder has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission and (B) no contribution will be made under circumstances where the maker of such contribution would not have been required to indemnify the Indemnified Party under the fault standards set forth in this Section 5. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation.

The indemnity and contribution agreements contained in this Section 5 are in addition to any liability that the Indemnifying Parties may have to the Indemnified Parties and are not in diminution or limitation of the indemnification provisions under the Purchase Agreement.

6. Miscellaneous.

(a) Remedies. In the event of a breach by the Company or by a Holder of any of their obligations under this Agreement, each Holder or the Company, as the case may be, in addition to being entitled to exercise all rights granted by law and under this Agreement, including recovery of damages, will be entitled to specific performance of its rights under this Agreement. The Company and each Holder agree that monetary damages would not provide adequate compensation for any losses incurred by reason of a breach by it of any of the provisions of this Agreement and hereby further agrees that, in the event of any action for specific performance in respect of such breach, it shall waive the defense that a remedy at law would be adequate.

(b) No Piggyback on Registrations; Prohibition on Filing Other Registration Statements. Except and to the extent specified in the Purchase Agreement, neither the Company nor any of its security holders (other than the Holders in such capacity pursuant hereto) may include securities of the Company in a Registration Statement other than the Registrable Securities and the Company shall not prior to the Effective Date enter into any agreement providing any such right to any of its security holders.

(c) Compliance. Each Holder covenants and agrees that it will comply with the prospectus delivery requirements of the Securities Act as applicable to it (unless an exemption therefrom is available) in connection with sales of Registrable Securities pursuant to the Registration Statement and shall sell the Registrable Securities only in accordance with a method of distribution described in the Registration Statement.

(d) Discontinued Disposition. By its acquisition of Registrable Securities, each Holder agrees that, upon receipt of a notice from the Company of the occurrence of any event of the kind described in Section 3(c)(iii)-(vi), such Holder will forthwith discontinue disposition of such Registrable Securities under a Registration Statement until it is advised in writing (the "Advice") by the Company that the use of the applicable Prospectus (as it may have been supplemented or amended) may be resumed. The Company will use its commercially reasonable efforts to ensure that the use of the Prospectus may be resumed as promptly as is practicable.

(e) No Inconsistent Agreements. Neither the Company nor any of its Subsidiaries has entered, as of the date hereof, nor shall the Company or any of its Subsidiaries, on or after the date hereof, enter into any agreement with respect to its securities, that would have the effect of impairing the rights granted to the Holders in this Agreement or otherwise conflicts with the provisions hereof.

(f) Amendments and Waivers. The provisions of this Agreement, including the provisions of this sentence, may not be amended, modified or supplemented, or waived unless the same shall be in writing and signed by the Company and Holders holding no less than a majority of the then outstanding Registrable Securities, provided that any party may give a waiver as to itself. Notwithstanding the foregoing, a waiver or consent to depart from the provisions hereof with respect to a matter that relates exclusively to the rights of Holders and that does not directly or indirectly affect the rights of other Holders may be given by Holders of all of the Registrable Securities to which such waiver or consent relates; *provided, however*, that the provisions of this sentence may not be amended, modified, or supplemented except in accordance with the provisions of the immediately preceding sentence.

(g) Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be delivered as set forth in the Purchase Agreement.

(h) Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the successors and permitted assigns of each of the parties and shall inure to the benefit of each Holder. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. The Company may not assign its rights (except by merger or in connection with another entity acquiring all or substantially all of the Company's assets) or obligations hereunder without the prior written consent of all the Holders of the then outstanding Registrable Securities. Each Holder may assign its respective rights hereunder in the manner and to the Persons as permitted under the Purchase Agreement; provided in each case that (i) the Holder agrees in writing with the transferee or assignee to assign such rights and related obligations under this Agreement, and for the transferee or assignee to assume such obligations, and a copy of such agreement is furnished to the Company within a reasonable time after such assignment, (ii) the Company is, within a reasonable time after such transfer or assignment, furnished with written notice of the name and address of such transferee or assignee and the securities with respect to which such registration rights are being transferred or assigned, (iii) at or before the time the Company received the written notice contemplated by clause (ii) of this sentence, the transferee or assignee agrees in writing with the Company to be bound by all of the provisions contained herein and (iv) the transferee is an "accredited investor," as that term is defined in Rule 501 of Regulation D.

(i) Execution and Counterparts. This Agreement may be executed in two or more counterparts, each of which when so executed shall be deemed to be an original and, all of which taken together shall constitute one and the same Agreement and shall become effective when counterparts have been signed by each party and delivered to the other party, it being understood that both parties need not sign the same counterpart. In the event that any signature is delivered by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such ".pdf" signature were the original thereof.

(j) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be determined in accordance with the provisions of the Purchase Agreement.

(k) Cumulative Remedies. The remedies provided herein are cumulative and not exclusive of any other remedies provided by law.

(l) Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their good faith reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

(m) Headings. The headings in this Agreement are for convenience only and shall not limit or otherwise affect the meaning hereof.

(n) Independent Nature of Purchasers' Obligations and Rights. The obligations of each Purchaser under this Agreement are several and not joint with the obligations of any other Purchaser hereunder, and no Purchaser shall be responsible in any way for the performance of the obligations of any other Purchaser hereunder. The decision of each Purchaser to purchase the Shares pursuant to the Purchase Agreement has been made independently of any other Purchaser. Nothing contained herein or in any other agreement or document delivered at any closing, and no action taken by any Purchaser pursuant hereto or thereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert with respect to such obligations or the transactions contemplated by this Agreement. Each Purchaser acknowledges that no other Purchaser has acted as agent for such Purchaser in connection with making its investment hereunder and that no Purchaser will be acting as agent of such Purchaser in connection with monitoring its investment in the Shares or enforcing its rights under the Purchase Agreement. Each Purchaser shall be entitled to protect and enforce its rights, including, without limitation, the rights arising out of this Agreement, and it shall not be necessary for any other Purchaser to be joined as an additional party in any Proceeding for such purpose. The Company acknowledges that each of the Purchasers has been provided with the same Registration Rights Agreement for the purpose of closing a transaction with multiple Purchasers and not because it was required or requested to do so by any Purchaser.

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above. IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written

ADICET BIO, INC.

By: /s/ Chen Schor

Name: Chen Schor

Title: President and Chief Executive Officer

ACTIVE/102380788.4

SUBSIDIARIES

Subsidiary	Jurisdiction of Incorporation
Adicet Therapeutics, Inc.	Delaware
Adicet Bio Israel Ltd.	Israel

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Adicet Bio, Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-250033, 333-249275, 333-237123, 333-230363, and 333-222746) on Form S-8 of Adicet Bio, Inc. (formerly resTORbio, Inc.) of our report dated March 11, 2021, with respect to the consolidated balance sheet of Adicet Bio, Inc. and subsidiaries as of December 31, 2020, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for the year then ended, and the related notes, which report appears in the December 31, 2020 annual report on Form 10-K of Adicet Bio, Inc.

Our report refers to our audit of the adjustments to retrospectively apply the exchange ratio to the 2019 and 2018 consolidated financial statements, as more fully described in Note 2 to the consolidated financial statements. However, we were not engaged to audit, review, or apply any procedures to the 2019 and 2018 consolidated financial statements other than with respect to such adjustments.

Our report refers to a change in the method of accounting for leases as of January 1, 2020 due to the adoption of Accounting Standards Update No. 2016-02, *Leases (Topic 842)*.

/s/ KPMG LLP

Boston, Massachusetts
March 11, 2021

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in this Registration Statement on Form S-3 of Adicet Bio, Inc. of our report dated June 23, 2020 relating to the financial statements, which appears in Adicet Bio, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2020. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP

San Jose, California
March 11, 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, Chen Schor, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2020 of Adicet Bio, Inc. (the “registrant”);
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)

Dated: March 11, 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2020 of Adicet Bio, Inc. (the “registrant”);
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)

Dated: March 11, 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 Annual Report on Form 10-K of Adicet Bio, Inc. (the “Company”) for the fiscal year ended December 31, 2020 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)

Dated: March 11, 2021

/s/ Nick Harvey

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

Dated: March 11, 2021