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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, 2021

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

For the transition period from to .

Commission file number 001-36076

FATE THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**65-1311552**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
12278 Scripps Summit Drive, San Diego, California	**92131**
(Address of principal executive offices)	**(Zip Code)**

(858) 875-1800
(Registrant's telephone number, including area code)

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	**FATE**	**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 ☒ or No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ or 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 ☒ or 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

Indicate by check mark whether the registrant 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 Act). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $6,960,000,000 as of June 30, 2021 based upon the closing sale price on The Nasdaq Global Market reported for such date. Shares of common stock held by each executive officer and director and certain holders of more than 10% of the outstanding shares of the registrant's common stock have been excluded in that such persons may be deemed to be affiliates. Shares of common stock held by other persons, including certain other holders of more than 10% of the outstanding shares of common stock, have not been excluded in that such persons are not deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of February 24, 2022 was 96,427,693.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, on or before the date 120 days after the conclusion of the registrant's fiscal year ended December 31, 2021 pursuant to Regulation 14A in connection with the registrant's 2022 Annual Meeting of Stockholders are incorporated by reference into Part III of this annual report on Form 10-K.

FATE THERAPEUTICS, INC.
Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2021

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RISK FACTOR SUMMARY

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC before making investment decisions regarding our common stock.

- Our product candidates represent a novel therapeutic approach to treating cancer and may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences. If we fail to complete the preclinical or clinical development of, or to obtain regulatory approval for, our product candidates, our business would be significantly harmed.
- We use induced pluripotent stem cell technology and gene-editing technology in the creation of our product candidates. Both technologies are relatively new technologies, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval. If we are unable to use these technologies in the creation of our product candidates, our business would be significantly harmed.
- We may face delays in initiating, conducting or completing our clinical trials, including due to difficulties enrolling patients in our clinical trials, and we may not be able to initiate, conduct or complete them at all.
- Initial, interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. Furthermore, results from our ongoing or future clinical trials involving our product candidates may differ materially from initial, interim and preliminary data.
- The manufacture and distribution of our cell product candidates are complex and subject to a multitude of risks. These risks could substantially limit the clinical and commercial supply of our product candidates and increase our costs, and the development and commercialization of our product candidates could be significantly delayed or restricted if the United States Food and Drug Administration (FDA) or other regulatory authorities impose additional requirements on our manufacturing operations or if we are required to change our manufacturing operations to comply with regulatory requirements.
- We have limited experience manufacturing our product candidates on a clinical scale, and no experience manufacturing on a commercial scale. Any failure by us or any third parties on whom we depend to manufacture our product candidates consistently and under the proper conditions may result in delays to our clinical development plans and impair our ability to obtain approval for, or commercialize, our product candidates.
- Our inability to manufacture sufficient quantities of our product candidates, or the loss of our third-party contract manufacturers, or our or their failure to supply sufficient quantities of our product candidates at acceptable quality levels or prices, or at all, would materially and adversely affect our business.
- We depend on third party suppliers, including sole source suppliers, for the provision of reagents, materials, devices and equipment that are used by us and our third-party contract manufacturers in the production of our product candidates, the loss of which could adversely impact our ability to conduct our clinical trials or commercialize our product candidates, if approved.
- The ongoing global coronavirus, SARS-CoV-2 (COVID-19), pandemic could adversely impact various aspects of our business, results of operations and financial condition, and could cause a disruption to our supply chain and the development and manufacture of our product candidates.
- We may face challenges recruiting and retaining key personnel due to labor market changes, availability of qualified candidates, and competition for employees from other companies.
- We may face cost fluctuations and inflationary pressures, including increases in prices of materials and costs of labor, which may adversely impact our operating performance, expenses, and results.
- We depend on strategic partnerships and collaboration arrangements for the development and commercialization of certain of our product candidates in certain indications or geographic territories, and if these arrangements are unsuccessful, this could result in delays and other obstacles in the development, manufacture or commercialization of any of our product candidates and materially harm our results of operations.

- Development of our product candidates will require substantial additional funding, without which we will be unable to complete preclinical or clinical development of, or obtain regulatory approval for, our product candidates.
- We have a limited operating history, have incurred significant losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future.
- If we are unable to protect our intellectual property, or obtain and maintain patent protection for our technology and product candidates, other companies could develop products based on our discoveries, which may reduce demand for our products and harm our business.
- If we fail to comply with our obligations under our license agreements, we could lose rights to our product candidates or key technologies.
- We may not be successful in obtaining or maintaining necessary rights to product components and processes for development or manufacture of our product candidates which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.
- We do not have experience marketing any product candidates and do not have a sales force or distribution capabilities, and if our products are approved, we may be unable to commercialize them successfully.
- The commercial success of our product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payers and others in the medical community and may require additional generation of evidence development around areas like the anticipated budget impact, comparative costs and benefits relative to standard of care and other value demonstrations.
- We face increasing competition in an environment of rapid technological change from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- The success of our existing product candidates is substantially dependent on developments within the field of cellular immunotherapy, some of which are beyond our control.
- Security breaches, loss of data and other disruptions could compromise sensitive information related to our business.
- Our principal stockholders and management own a significant percentage of our stock and may be able to exercise significant control over our company.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section entitled "Risk Factors" and the other information set forth in this annual report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

FORWARD–LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, even if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our plans to research, develop and commercialize our product candidates;
- the initiation, progress, success, cost and timing of our clinical trials and product development activities;
- our ability and timing to advance our product candidates in, and to successfully initiate, conduct, enroll and complete, clinical trials;
- the therapeutic potential of our product candidates, and the disease indications for which we intend to develop our product candidates;
- the timing and likelihood of, and our ability to obtain and maintain, regulatory clearance of our Investigational New Drug (IND) applications for and regulatory approval of our product candidates;
- the potential of our technology platform, including our induced pluripotent stem cell (iPSC) product platform, and our ability to leverage our platform in our research, development and commercialization activities for our product candidates;
- our ability to manufacture our product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture;
- our ability to source clinical and, if approved, commercial materials and supplies used to manufacture our product candidates;
- the performance of third parties in connection with the development and manufacture of our product candidates, including third parties conducting our clinical trials as well as third-party suppliers and manufacturers;
- our ability to attract and retain strategic collaborators with development, regulatory and commercialization expertise;
- the potential benefits of strategic collaboration agreements and our ability, and the ability of our collaborators, to successfully develop product candidates under the respective collaborations;
- our ability to obtain funding for our operations, including funding necessary to initiate and complete clinical trials of our product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with actual or potential collaborators, to commercialize our product candidates, if approved;
- our ability to successfully commercialize our product candidates, if approved;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments and approval pathways in the United States and foreign countries for our product candidates;
- the potential scope and value of our intellectual property rights;
- our ability, and the ability of our licensors, to obtain, maintain, defend and enforce intellectual property rights protecting our product candidates, and our ability to develop and commercialize our product candidates without infringing the proprietary rights of third parties;
- our ability to recruit and retain key personnel;
- the accuracy of our projections and estimates regarding our revenues, expenses, capital requirements, cash utilization and need for additional financing;

- developments relating to our competitors and our industry; and
- other risks and uncertainties, including those described under Part I, Item 1A. Risk Factors of this Annual Report on Form 10-K.

Any forward-looking statements in this Annual Report on Form 10-K reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part I, Item 1A. Risk Factors and elsewhere in this Annual Report on Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

In this Annual Report on Form 10-K, unless the context requires otherwise, "Fate Therapeutics," "Company," "we," "our," and "us" means Fate Therapeutics, Inc. and its subsidiaries.

PART I

ITEM 1. Business

Overview

We are a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for patients with cancer. We are developing first-in-class cell therapy product candidates based on a simple notion: we believe that better cell therapies start with better cells.

To create better cell therapies, we use a therapeutic approach that we generally refer to as cell programming. We use human induced pluripotent stem cells (iPSCs) to generate a clonal master iPSC line having preferred biological properties, and we direct the fate of the clonal master iPSC line to create our cell therapy product candidate. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, we believe clonal master iPSC lines can be used as a renewable source for manufacturing cell therapy products which are well-defined and uniform in composition, can be repeatedly mass produced at significant scale in a cost-effective manner, and can be delivered off-the-shelf to treat many patients.

Utilizing this therapeutic approach, we are advancing a pipeline of programmed cellular immunotherapies, including off-the-shelf natural killer (NK) and T-cell product candidates derived from clonal master iPSC lines for the treatment of cancer. The following table summarizes our programmed cellular immunotherapies currently under development:

Program	Cell Type *Functionality*	Target(s)	Indication(s)	Research	Preclin	Phase 1	Phase 2	Phase 3
FT516	iNK *hnCD16*	CD20	BCL + CD20 mAb	Hematology				
		n/a	AML					
FT596	iNK *hnCD16 + IL15RF + CAR-19*	CD19, CD20	BCL, CLL ± CD20 mAb					
FT538	iNK *hnCD16 + IL15RF + CD38-KO*	n/a	AML					
		CD38	MM + CD38 mAb					
		EGFR, HER2, PD1/PD-L1	Solid tumors + mAb	Solid Tumor				
FT576	iNK *hnCD16 + IL15RF + CD38-KO + CAR-BCMA*	BCMA, CD38	MM ± CD38 mAb					
FT819	iT *CAR-19, TCR-KO*	CD19	Hematology					
FT536	iNK *hnCD16 + IL15RF + CD38-KO + CAR-MICA/B*	MICA/B	Solid tumors ± mAb					
FT573	iNK *hnCD16 + IL15RF + CD38-KO + CAR-B7H3*	B7H3	Solid tumors ± mAb					
Janssen	iNK, iT	undisclosed	≤ 4 tumor targets					
Ono	iT	undisclosed	1 tumor target					

iPSC *= induced pluripotent stem cell* ***iNK*** *= iPSC-derived NK Cell* ***iT*** *= iPSC-derived T cell* ***mAb*** *= monoclonal antibody* ***CPI*** *= checkpoint inhibitor*
hnCD16 *= high affinity, non-cleavable CD16 Fc receptor* ***IL15-RF*** *= IL15 receptor fusion* ***CD38-KO*** *= CD38 knock-out* ***CAR*** *= chimeric antigen receptor* ***TCR-KO*** *= T-cell receptor knock-out*
AML *= acute myelogenous leukemia* ***BCL*** *= B-cell lymphoma* ***CLL*** *= chronic lymphocytic leukemia* ***MM*** *= multiple myeloma*

Our Approach

The use of human cells as therapeutic entities has disease-transforming potential, and compelling evidence of medical benefit for cell therapy exists across a broad spectrum of severe, life-threatening diseases. Clinical investigation of cell-based cancer immunotherapy has been rapidly expanding. One particular form of cell-based cancer immunotherapy, chimeric antigen receptor (CAR) T-cell therapy, has emerged as a revolutionary and potentially curative therapy for patients with certain hematologic malignancies, including refractory cancers. In fact, multiple CAR T-cell therapies have now been approved by the United States Food and Drug Administration (FDA) for the treatment of relapsed / refractory B-cell precursor acute lymphoblastic leukemia (ALL), relapsed / refractory diffuse large B-cell lymphoma (DLBCL), and relapsed / refractory multiple myeloma (MM).

Cell-based cancer immunotherapies undergoing clinical investigation today most often rely on the use of autologous, or a patient's own, cells. The requirement to source, engineer, expand and deliver cells patient-by-patient is logistically complex, resource intensive and expensive, and can result in significant batch-to-batch variability in product identity, purity and potency as well as in manufacturing failures. Significant hurdles remain to ensure that cell-based cancer immunotherapies can be consistently manufactured and reliably delivered, in a cost-effective manner and at the scale necessary, to support broad patient access and wide-spread commercialization.

Rather than rely on the use of a patient's own cells, we seek to use clonal master iPSC lines to manufacture, develop and commercialize first-in-class cellular immunotherapies. We believe our approach has the potential to improve cell product consistency and potency, reduce manufacturing costs, shorten time to treatment and reach more patients.

Our Strategy

The key pillars of our strategy are to:

- **Exploit our leadership position in iPSC technology to develop and commercialize off-the-shelf cell products for the treatment of cancer.** Human iPSCs, with their unique capacity to be indefinitely expanded and differentiated in culture into any type of cell in the body, hold revolutionary potential for creating better cell therapies. The groundbreaking discovery that fully differentiated human cells can be induced to a pluripotent state through the expression of certain genes was recognized with the 2012 Nobel Prize in Science and Medicine. We believe iPSCs can be used to overcome key limitations inherent in many of the cell therapy product candidates undergoing development today, including the requirement to source, isolate, engineer and expand cells from an individual patient or healthy donor with each batch of production. These batch-to-batch manufacturing requirements are logistically complex and expensive, and can result in variable cell product identity, purity and potency as well as manufacturing failures.

  We are applying our expertise in iPSC biology to genetically engineer, isolate and select single-cell iPSCs for clonal expansion, characterization and cryopreservation as clonal master iPSC lines. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, we believe clonal master iPSC lines can be made and used as a renewable source for manufacturing cell therapy products which are well-defined and uniform in composition, can be repeatedly mass produced at significant scale in a cost-effective manner, and can be delivered off-the-shelf to treat many patients.

  We have amassed significant expertise in the manufacture of NK cells and T cells from clonal master iPSC lines. Our expertise includes: generating, engineering, isolating and characterizing single-cell iPSC clones; creating and cryopreserving clonal master iPSC lines; differentiating these clonal master cell iPSC lines to produce NK cells and T cells; and regulatory affairs experience to enable clinical investigation of iPSC-derived cell products. We believe our iPSC-derived NK cell and T-cell product candidates have the potential to be administered in multi-dose, multi-cycle treatment regimens, including in combination with other cancer treatments, to drive deeper and more durable responses.

- **Forge collaborations with leading researchers and top medical centers to accelerate development of and rapidly translate our iPSC-derived cell product candidates into first-in-human clinical trials.** The research and development of iPSC-derived cell product candidates requires an exceptional team of people and scientific, manufacturing and clinical expertise across a range of disciplines. We have and will continue to seek collaborations with leading researchers, investigators and top medical centers for the research, development, manufacture and clinical translation of our iPSC-derived cell product candidates. Among our collaborations is a research partnership with the University of Minnesota, led by Dr. Jeffrey S. Miller, a renowned NK cell biologist and clinical investigator, to support the development of certain of our iPSC-derived NK cell product candidates. We also have a research partnership with Memorial Sloan Kettering Cancer Center, led by Dr. Michel Sadelain, a renowned T-cell biologist and a recognized founder of CAR T-cell therapy, to support the development of our iPSC-derived CAR T-cell product candidates. We believe this approach to research and development will maximize our potential to successfully build our iPSC product platform, accelerate the clinical translation and clinical investigation of our iPSC-derived cell product candidates, and efficiently establish clinical proof-of-concept for our iPSC-derived cell product candidates.
- **Selectively share our iPSC product platform with industry-leading strategic partners for the development of iPSC-derived cell therapies.** The research, development and clinical investigation of cell therapies for the treatment of human diseases is rapidly expanding. We believe we are uniquely positioned as an expert partner of choice for industry-leading developers seeking to develop iPSC-derived cell therapies for the treatment of human diseases, including cancer. For example, we are collaborating with Ono Pharmaceutical Co. Ltd. (Ono) to develop and commercialize off-the-shelf, iPSC-derived CAR T-cells for the treatment of certain solid tumors, and we are collaborating with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson, to develop and commercialize off-the-shelf, iPSC-derived CAR NK cell and CAR T-cell product candidates for the treatment of certain hematologic

malignancies and solid tumors. Since iPSCs have the unique capacity to be genetically engineered, indefinitely expanded and differentiated in culture into any type of cell in the body, we believe there is significant opportunity to broadly exploit our industry-leading iPSC product platform and intellectual property position in other disease areas beyond cancer. We will continue to seek partnerships with institutions and companies for the research, development and commercialization of iPSC-derived cell therapies for the treatment of human diseases.

- **Efficiently develop and commercialize first-in-class cellular immunotherapies for severe, life-threatening diseases where treatment options are limited.** We are clinically developing first-in-class cellular immunotherapies to improve the lives of patients with severe, life-threatening diseases, where the unmet need is significant and where regulatory agencies offer efficient and expedited development and review programs. For example, in December 2021, the FDA granted regenerative medicine advanced therapy (RMAT) designation to FT516 for the treatment of relapsed / refractory DLBCL. The RMAT program provides for early interactions with the FDA to discuss potential pathways for accelerated approval. Due to high incidences of morbidity and mortality and the rare disease nature of certain of our target indications, we believe clinical trials that we conduct will generally require relatively small numbers of subjects and that our development path to approval may be efficient.

Our Off-the-shelf, iPSC-derived Cellular Immunotherapy Pipeline

NK cells have an innate ability to rapidly seek and destroy abnormal cells, such as cancer or virally-infected cells, and represent one of the body's first lines of immunological defense. NK cells have the unique ability to selectively identify and destroy abnormal cells through multiple mechanisms while leaving normal healthy cells unharmed. These cytotoxic mechanisms include: direct innate killing by binding to stress ligands expressed by abnormal cells and releasing toxic granules; indirect killing by producing and releasing proinflammatory and chemotactic cytokines that play a pivotal role in orchestrating the adaptive immune response; and antibody-mediated targeted killing by binding to and enhancing the cancer-killing effect of endogenous and therapeutic antibodies through a process known as antibody-dependent cellular cytotoxicity (ADCC).

T cells, or T-lymphocytes, play a critical role in adaptive immunity and are distinguished from other cells of the immune system by the presence of a T-cell receptor (TCR) on their surface. TCRs are generated by DNA rearrangement and positively selected for their capacity to engage host major histocompatibility complex (MHC) molecules. The majority of T cells, termed alpha beta T cells (αβ T cells), rearrange their alpha and beta chains on the TCR, which confers specificity and enables T cells to recognize non-self molecules, known as non-self antigens, expressed on the surface of transformed or foreign cells. Antigens inside a cell are bound to, and are routinely brought to the surface of a cell, by MHC class I molecules. Upon antigen recognition, T cells bind to the MHC-antigen complex, become activated and destroy the targeted cell. Unlike NK cells, T cells are limited by antigen-specific binding of their TCR in order to induce cellular cytotoxicity.

We are developing off-the-shelf, iPSC-derived NK cell and T-cell cancer immunotherapies, including cell product candidates intended to synergize with checkpoint inhibitor and monoclonal antibody therapies and to target tumor-associated antigens.

FT516: iPSC-derived, hnCD16 Engineered NK Cell Product Candidate

NK cells play a major role in the anti-tumor activity of certain tumor-targeting antibodies. NK cells express CD16, an activating receptor that binds to the Fc domain of IgG antibodies. Once activated through CD16, NK cells are able to destroy antibody-coated tumor cells and secrete cytokines, such as interferon gamma, to potentiate an adaptive immune response. This mechanism of action, referred to as antibody-dependent cellular cytotoxicity (ADCC), is believed to be important for the treatment of a wide range of cancers.

CD16 consists of two genomic variants, 158V and 158F, that confer high or low binding affinity, respectively, to the Fc domain of IgG antibodies. Numerous clinical studies with FDA-approved tumor-targeting antibodies, including rituximab (FDA-approved for certain cancers of the blood and lymphatic system), trastuzumab (FDA-approved for certain breast and gastric cancers) and cetuximab (FDA-approved for certain head and neck, non-small cell lung and colorectal cancers), have demonstrated that patients homozygous for the 158V variant, which is present in only about 15% of patients, have improved clinical outcomes. In addition, the expression of CD16 on NK cells has been shown to undergo considerable down-regulation in cancer patients, which can significantly limit anti-tumor activity.

FT516 is an investigational off-the-shelf NK cell cancer immunotherapy derived from a clonal master iPSC line engineered to express a novel CD16 (hnCD16) Fc receptor. Our novel CD16 Fc receptor incorporates two unique features designed to augment the anti-tumor activity of FT516: a high-affinity homozygous 158V variant to promote high binding affinity and a modification to block its cleavage and down-regulation upon NK cell activation.

We are studying FT516 in an ongoing, multi-center Phase 1 clinical trial. To our knowledge, FT516 is the first-ever engineered iPSC-derived cell therapy cleared for clinical investigation in the United States. The Phase 1 trial is designed to assess the safety and

determine the maximum dose of FT516 in adult patients with selected hematologic malignancies. The trial assesses two treatment regimens: FT516 as a monotherapy in patients with relapsed / refractory acute myeloid leukemia (AML) testing three separate dose cohorts (90 million cells per dose; 300 million cells per dose; 900 million cells per dose) (Regimen A); and FT516 in combination with CD20-targeted monoclonal antibody therapy in patients with advanced B-cell lymphoma (BCL) who have previously failed or progressed on CD20-targeted monoclonal antibody therapy testing four separate dose cohorts (30 million cells per dose; 90 million cells per dose; 300 million cells per dose; 900 million cells per dose) (Regimen B). The treatment schedule consists of outpatient lympho-conditioning chemotherapy (cyclophosphamide and fludarabine), CD20-targeted monoclonal antibody therapy (Regimen B only), and three once-weekly doses of FT516 each with IL-2 cytokine support. For those patients who are clinically stable at Day 29, a second treatment cycle may be administered.

We have reported interim Phase 1 clinical data for both Regimen A in relapsed / refractory AML and Regimen B in relapsed / refractory BCL:

- *Interim Phase 1 Clinical Data in AML.* We have reported interim Phase 1 clinical data for nine patients with relapsed / refractory AML treated with FT516 as monotherapy in the first and second dose cohorts (90 million and 300 million cells per dose, respectively) as of an April 16, 2021 cutoff date. No dose-limiting toxicities (DLTs) and no events of any grade of cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), or graft-versus-host disease (GvHD) were reported by investigators. Six of the nine patients showed anti-leukemia activity following treatment with FT516 as evidenced by on-treatment reductions in bone marrow blasts, with four patients achieving an objective response reflecting complete clearance of leukemic blasts in the bone marrow. Three of the four responding patients achieved a best overall response of complete remission with incomplete hematologic recovery (CRi) based on 2017 ELN response criteria. We have completed dose escalation in Regimen A.
- *Interim Phase 1 Clinical Data in BCL.* We have reported interim Phase 1 clinical data for twenty patients with relapsed / refractory BCL treated with FT516 in combination with rituximab in the first, second, third, and fourth dose cohorts (30 million, 90 million, 300 million, and 900 million cells per dose, respectively) as of an October 18, 2021 cutoff date. No DLTs and no events of any grade of CRS, ICANS, or GvHD were reported by investigators. Of the 18 patients treated in the second, third, and fourth dose cohorts, 10 patients were naïve to treatment with autologous CD19-targeted chimeric antigen receptor (CAR) T-cell therapy and eight patients were previously treated with autologous CD19-targeted CAR T-cell therapy. Of the 10 patients naïve to treatment with CAR T-cell therapy, eight patients achieved an objective response (80%), including five patients who achieved a complete response (50%), as assessed by PET-CT scan per Lugano 2014 criteria. Of the eight patients previously treated with CAR T-cell therapy, three patients achieved an objective response (38%), all of which were complete responses, as assessed by PET-CT scan per Lugano 2014 criteria. All 11 responding patients continued in ongoing response at three months following initiation of treatment (61%), and eight of these patients continued in ongoing response (44%) as of the data cutoff date at a median follow-up of 8.3 months.

We have completed dose escalation in Regimen B, and have initiated the dose-expansion stage of our Phase 1 study for the treatment of relapsed / refractory BCL at 900 million cells per dose. We are enrolling patients in three disease-specific expansion cohorts: patients with relapsed / refractory aggressive lymphomas who have previously been treated with CD19-targeted CAR T-cell therapy; patients with relapsed / refractory aggressive lymphomas who are naïve to treatment with CD19-targeted CAR T-cell therapy; and patients with relapsed / refractory follicular lymphoma. In addition, we are also enrolling patients in an expansion cohort, without fludarabine and cyclophosphamide based lympho-conditioning chemotherapy that combines FT516 with rituximab-bendamustine (R-Benda), a standard-of-care regimen for the treatment of BCL.

In December 2021 we announced regenerative medicine advanced therapy (RMAT) Designation was granted by the FDA to FT516 for relapsed/refractory DLBCL. RMAT designation is an FDA program designed to expedite the development and review of regenerative medicine therapies, including cell-based cancer immunotherapies, that have demonstrated the potential to address an unmet medical need based on preliminary clinical evidence. The program allows for early and frequent interactions with the FDA, and enables regulatory authority guidance on efficient drug development, pathways for accelerated approval, and approaches to fulfill post-approval requirements. We plan to engage with the FDA to discuss CMC, manufacturing, and clinical development considerations for late-stage development of FT516, including pathways for accelerated approval.

FT596: iPSC-derived, hnCD16, CAR19, IL15-RF Engineered NK Cell Product Candidate

CAR T-cell therapy has recently emerged as a revolutionary and potentially curative therapy for patients with certain hematologic malignancies, including refractory cancers. Since 2017, three CAR T-cell therapies have been approved by the FDA for the treatment of relapsed / refractory B-cell precursor acute lymphoblastic leukemia (ALL) and relapsed / refractory diffuse large B-cell lymphoma (DLBCL). While most researchers and clinical investigators continue to focus on the development of autologous or allogeneic CAR T-cell therapies, we are developing CAR NK cell product candidates derived from clonal master engineered iPSC lines as off-the-shelf cancer immunotherapies for the treatment of hematologic malignancies and solid tumors.

FT596 is an investigational off-the-shelf CAR NK cell cancer immunotherapy derived from a clonal engineered master iPSC line. FT596 incorporates three anti-tumor functional modalities: a proprietary CAR optimized for NK cell biology that targets B-cell antigen CD19; a novel high-affinity, non-cleavable CD16 (hnCD16) Fc receptor that has been modified to augment antibody-dependent cellular cytotoxicity, enabling targeting of tumor-associated antigens such as CD20; and an IL-15/IL-15 receptor fusion (IL-15RF), a potent cytokine complex that promotes survival, proliferation and trans-activation of NK cells and CD8 T cells. Together, these features are intended to enable multi-antigen targeting, of malignant B cells, augment ADCC, and enhance cell persistence.

We are studying FT596 in an ongoing, multi-center Phase 1 clinical trial for the treatment of relapsed / refractory B-cell malignancies. The Phase 1 trial is designed to assess the safety and determine the maximum dose of FT596 in adult patients. The trial includes five treatment regimens, each enrolling patients in up to four dose cohorts (30 million cells per dose; 90 million cells per dose; 300 million cells per dose and 900 million cells per dose): FT596 as a monotherapy for patients with relapsed / refractory B-cell lymphoma (BCL) (Regimen A1); FT596 in combination with rituximab for patients with relapsed / refractory BCL (Regimen B1); FT596 in combination with obinutuzumab for patients with relapsed / refractory follicular lymphoma (FL) (Regimen B2); FT596 as a monotherapy for patients with relapsed / refractory chronic lymphocytic leukemia (CLL) (Regimen A2); and FT596 in combination with obinutuzumab for patients with relapsed / refractory CLL (Regimen B3). The treatment schedule consists of outpatient lympho-conditioning chemotherapy (cyclophosphamide and fludarabine), CD20-targeted monoclonal antibody therapy (Regimens B1, B2, and B3 only), and up to two doses of FT596. For those patients with evidence of clinical benefit at Day 29, a second treatment cycle may be administered.

At the ASH 2021 Annual Meeting, we have reported interim Phase 1 clinical data for both Regimens A1 and B1 as of an October 11, 2021 cutoff date:

- *Interim Phase 1 Clinical Data in Regimen A1*. We have reported interim Phase 1 clinical data for 12 patients with relapsed / refractory BCL treated with FT596 as monotherapy in the first, second, and third single-dose cohorts (30 million, 90 million, and 300 million cells, respectively). No DLTs and no events of any grade of ICANS or GvHD were reported by investigators. One low-grade adverse event (Grade 1) of CRS was reported, which was of limited duration and resolved without intensive care treatment. Of the 12 patients treated in the first (n=3), second (n=4), and third (n=5) dose cohorts, eight patients achieved an objective response (67%), including three patients who achieved a complete response (25%), as assessed by PET-CT scan per Lugano 2014 criteria. Of the nine patients treated in the second and third dose cohorts, seven patients achieved an objective response (78%), including three patients who achieved a complete response (33%), as assessed by PET-CT scan per Lugano 2014 criteria. Of the seven responding patients, five patients were treated with a second FT596 single-dose cycle and continued in ongoing response at a median follow-up of 4.1 months, including one patient in ongoing complete response at 8.1 months; one patient was treated with only one FT596 single-dose cycle, reached six months in complete response, and subsequently had disease progression at 6.5 months; and one patient was treated with only one FT596 single-dose cycle and had disease progression at 1.7 months.
- *Interim Phase 1 Clinical Data in Regimen B1*. We have reported interim Phase 1 clinical data for 12 patients with relapsed / refractory BCL treated with FT596 in combination with rituximab in the first, second, and third single-dose cohorts (30 million, 90 million, and 300 million cells, respectively). No DLTs and no events of any grade of ICANS or GvHD were reported by investigators. Two low-grade adverse events (one Grade 1; one Grade 2) of CRS were reported, which were of limited duration and resolved without intensive care treatment. Of the 12 patients treated in the first (n=3), second (n=4), and third (n=5) dose cohorts, six patients achieved an objective response (50%), including five patients who achieved a complete response (42%), as assessed by PET-CT scan per Lugano 2014 criteria. Of the nine patients treated in the second and third dose cohorts, six patients achieved an objective response (67%), including five patients who achieved a complete response (56%), as assessed by PET-CT scan per Lugano 2014 criteria. All six responding patients were treated with a second FT596 single-dose cycle. Five responding patients continued in ongoing response at a median follow-up of 4.6 months, including two patients in ongoing complete response at 6.0 and 10.8 months; and one responding patient reached six months in complete response and subsequently had disease progression at 6.7 months.

Subsequent to the October 11, 2021 cutoff date, data from eight additional patients were reported, including an additional patient in the third single-dose cohort of Regimen B1 who was evaluable for initial anti-tumor response, and seven patients in the fourth single-dose cohorts (n=1 in Regimen A1; n=6 in Regimen B1) who were evaluable for safety and initial anti-tumor response. No DLTs and no events of any grade of CRS, ICANS or GvHD were reported by investigators. Of these eight patients, five patients – all of whom were treated in the fourth single-dose cohort of Regimen B1 – achieved an objective response, including four patients who achieved a complete response, as assessed by PET-CT scan per Lugano 2014 criteria following completion of the first FT596 single-dose cycle.

Enrollment in the dose-escalation stage is currently ongoing in Regimens A1 and B1 in relapsed / refractory BCL and in Regimens A2 and B3 in relapsed / refractory CLL.

In April 2020, the FDA allowed a second IND application for the clinical investigation of FT596 for the prevention of relapse in patients with BCL who have undergone autologous hematopoietic stem cell transplant (HSCT) and are considered high risk for early relapse. The Phase 1 clinical trial, which is sponsored by investigators from the Masonic Cancer Center, University of Minnesota, is designed to assess the safety and determine the maximum dose of FT596 in combination with CD20-targeted monoclonal antibody therapy. The ongoing clinical trial is expected to enroll up to 18 patients in up to three dose cohorts (90 million cells per dose; 300 million cells per dose and 900 million cells per dose). FT596 is administered as a single dose with CD20-targeted monoclonal antibody therapy approximately 30 days following HSCT.

FT538: iPSC-derived, hnCD16, IL15-RF, CD38KO Engineered NK Cell Product Candidate

Multiple myeloma is a hematologic malignancy characterized by the proliferation of malignant plasma cells. In multiple myeloma, malignant plasma cells accumulate in the bone marrow and produce abnormal antibodies called M proteins, which can cause kidney damage, bone destruction, and impaired immune function. While multiple approved drugs with novel mechanisms have improved disease management over the past decade, multiple myeloma is rarely curable and a significant majority of patients are expected to relapse.

Daratumumab is an IgG1 monoclonal antibody approved by the FDA in November 2015 for the treatment of multiple myeloma. Daratumumab effectively targets CD38, which is expressed on multiple myeloma cells, and induces cell death through multiple mechanisms, including ADCC. However, because CD38 is also expressed on activated NK cells, daratumumab treatment can induce NK cell fratricide, which may impair the effectiveness of ADCC. In addition, NK cell function is often suppressed or absent in patients with multiple myeloma as a result of the cancer itself as well as treatment therapy, further reducing the effectiveness of daratumumab. Collectively, preclinical and clinical observations suggest a potential therapeutic benefit of maintaining NK cell numbers and function to support ADCC in patients with multiple myeloma.

FT538 is an investigational off-the-shelf NK cell cancer immunotherapy derived from a clonal engineered master iPSC line. FT538 incorporates three functional modifications: a novel high-affinity, non-cleavable CD16 (hnCD16) Fc receptor that has been modified to augment ADCC; an IL-15/IL-15 receptor fusion (IL-15RF), a potent cytokine complex that promotes survival, proliferation and trans-activation of NK cells and CD8 T cells; and the complete elimination of CD38 expression to mitigate the potential for NK cell fratricide. Together, these features are intended to augment ADCC, enhance cell persistence and prevent anti-CD38 monoclonal antibody-induced fratricide.

We are studying FT538 in an ongoing, multi-center Phase 1 clinical trial designed to assess the safety and determine the maximum dose of FT538 in up to 105 adult patients. The trial includes two treatment regimens, each enrolling patients in up to four dose cohorts (100 million cells per dose; 300 million cells per dose; 1 billion cells per dose; and 1.5 billion cells per dose): FT538 as monotherapy for patients with relapsed / refractory AML (Regimen A); and FT538 in combination with daratumumab for patients with relapsed / refractory multiple myeloma who have failed at least two lines of therapy (Regimen B). The treatment schedule consists of outpatient lympho-conditioning chemotherapy (cyclophosphamide and fludarabine), daratumumab (Regimen B only), and three once-weekly doses of FT538. Dose escalation is currently ongoing in Regimens A and B.

We have reported interim Phase 1 clinical data for Regimen A in relapsed / refractory AML:

- *Interim Phase 1 Clinical Data in AML*. We have reported interim Phase 1 clinical data for three patients with relapsed / refractory AML treated with FT538 as monotherapy in the first dose cohort (100 million cells per dose) as of an April 16, 2021 cutoff date. Of the three patients enrolled in the first dose cohort, two were evaluable for safety and anti-leukemic activity and one patient discontinued from the study prior to completion of the first treatment cycle due to clinical evidence of failure to respond to therapy. No DLTs and no events of any grade of CRS, ICANS, or GvHD were reported by investigators. Both evaluable patients showed anti-leukemic activity following treatment with FT538 as evidenced by on-treatment reduction in bone marrow blasts, with one patient achieving a best overall response of CRi based on 2017 ELN response criteria.

The FDA also allowed a second IND application for the clinical investigation of FT538 for the treatment of relapsed / refractory AML. The Phase 1 clinical trial, which is sponsored and managed by investigators from the Masonic Cancer Center, University of Minnesota, is designed to assess the safety and determine the maximum dose of FT538 in combination with daratumumab in up to 50 adult patients. The treatment schedule consists of outpatient lympho-conditioning chemotherapy (cyclophosphamide and fludarabine), daratumumab, and three once-weekly doses of FT538. Enrollment in the dose-escalation stage is currently ongoing.

In March 2021, the FDA allowed our IND application for the clinical investigation of FT538 in combination with monoclonal antibody therapy for the treatment of advanced solid tumors. We are studying FT538 in an ongoing, multi-center Phase 1 clinical trial designed to assess the safety and determine the maximum dose of FT538 in up to 189 adult patients. The clinical protocol includes assessment of FT538 in combination with one of four monoclonal antibodies: EGFR-targeted cetuximab; HER2-targeted trastuzumab; PDL1-targeted avelumab; and PD1-targeted pembrolizumab. Each patient is eligible to receive up to two FT538 treatment cycles, with

each cycle consisting of outpatient lympho-conditioning chemotherapy (cyclophosphamide and fludarabine), monoclonal antibody therapy, and three once-weekly doses of FT538. Enrollment in the dose-escalation stage is currently ongoing.

FT576: iPSC-derived, hnCD16, IL15-RF, CD38-KO, CAR-BCMA Engineered NK Cell Product Candidate

In addition to CD38 targeting in multiple myeloma, targeting of other tumor-associated antigens expressed on malignant plasma cells has been explored. Of these antigens, the TNF-superfamily member B-cell Maturation Antigen (BCMA) is among the most researched and is under development by multiple groups as a CAR target. Several clinical trials in multiple myeloma have shown promising initial results targeting BCMA with CAR T cells; however, there remains significant opportunity to improve both rates of relapse and treatment of relapsed patients.

In August 2019, we entered into a license agreement with the Max Delbrück Center for Molecular Medicine (MDC) under which we were granted certain exclusive rights to intellectual property covering novel humanized CAR constructs that uniquely and specifically bind BCMA. In data published by MDC scientists, anti-BCMA CAR T cells equipped with its unique humanized extracellular antigen-binding domains show higher affinity and greater specificity than other anti-BCMA antigen-binding domains. These differentiated properties conveyed both greater selectivity in recognizing target B cells and more robust killing of target B cells *in vitro*, including malignant B cells with low expression levels of BCMA. Additionally, in *in vivo* proof-of-concept studies, MDC scientists demonstrated that anti-BCMA CAR T cells mediated anti-tumor activity in xenotransplant mouse models of multiple myeloma and of mature B-cell non-Hodgkin lymphoma, where BCMA surface expression is up to 4-fold lower as compared to mouse models of multiple myeloma.

FT576 is an investigational off-the-shelf NK cell cancer immunotherapy derived from a clonal engineered master iPSC line. FT576 incorporates four functional modifications: a proprietary CAR that targets BCMA; a novel high-affinity, non-cleavable CD16 (hnCD16) Fc receptor that has been modified to augment ADCC; an IL-15/IL-15 receptor fusion (IL-15RF), a potent cytokine complex that promotes survival, proliferation and trans-activation of NK cells and CD8 T cells; and the complete elimination of CD38 expression to mitigate the potential for NK cell fratricide. Together, these features are intended to enable multi-antigen targeting of myeloma cells, augment ADCC, enhance cell persistence and prevent anti-CD38 monoclonal antibody-induced fratricide.

We are studying FT576 in an ongoing, multi-center Phase 1 clinical trial designed to assess the safety and determine the maximum dose of FT576 following outpatient lympho-conditioning chemotherapy (cyclophosphamide and fludarabine) in up to 168 adult patients. The trial includes four treatment regimens: Regimen A as a single dose of FT576; Regimen A1 as two doses of FT576; Regimen B as a single dose of FT576 in combination with daratumumab; and Regimen B1 as two doses of FT576 in combination with daratumumab. Enrollment in the dose-escalation stage is currently ongoing.

FT536: iPSC-derived, hnCD16, IL15-RF, CD38-KO, CAR-MICA/B Engineered NK Cell Product Candidate

The major histocompatibility complex (MHC) class I related proteins A (MICA) and B (MICB) are induced by cellular stress, damage or transformation, and the expression of MICA and MICB proteins has been reported for many tumor types. Cytotoxic lymphocytes, such as NK cells and CD8+ T cells, can detect and bind the membrane-distal alpha-1 and -2 domains of MICA/B, activating a potent cytotoxic response. However, advanced cancer cells frequently evade immune cell recognition by proteolytic shedding of these domains. The clinical importance of proteolytic shedding is reflected in the association of high serum concentrations of shed MICA/B with disease progression in many solid tumors.

Several recent publications have shown that therapeutic antibodies targeting the membrane-proximal alpha-3 domain strongly inhibited MICA/B shedding, resulting in a substantial increase in the cell surface density of MICA/B and restoration of NK cell-mediated tumor immunity. In addition, a recent publication by scientists from Dana-Farber Cancer Institute (DFCI) demonstrated that cancers with B2M and JAK1 inactivating mutations resulting in loss of MHC class I expression can be effectively targeted with alpha-3 domain-specific antibodies to restore NK cell-mediated immunity against solid tumors resistant to cytotoxic T cells. Therapeutic approaches aimed at targeting the alpha-3 domain of MICA/B therefore represent a potentially promising novel strategy to overcome this prominent evasion mechanism as a means of restoring anti-tumor immunity in patients with solid tumors.

In April 2020, we entered into a license agreement with DFCI under which we were granted certain exclusive rights to intellectual property covering novel antibody fragments that uniquely and specifically bind the alpha-3 domain of MICA/B. FT536 is an investigational off-the-shelf NK cell cancer immunotherapy derived from a clonal engineered master iPSC line. FT536 incorporates four functional modifications: a proprietary CAR that targets the alpha-3 domain of MICA/B; a novel high-affinity, non-cleavable CD16 (hnCD16) Fc receptor that has been modified to augment ADCC; an IL-15/IL-15 receptor fusion (IL-15RF), a potent cytokine complex that promotes survival, proliferation and trans-activation of NK cells and CD8 T cells; and the complete elimination of CD38 expression to mitigate the potential for NK cell fratricide.

In December 2021, the FDA allowed our IND application for the clinical investigation of FT536 as monotherapy and in combination with monoclonal antibody therapy for the treatment of advanced solid tumors. We are initiating a multi-center Phase 1

clinical trial designed to assess the safety and determine the maximum dose of FT536. The clinical protocol includes assessment of FT536 in combination with one of five monoclonal antibodies: EGFR-targeted cetuximab; HER2-targeted trastuzumab; EGFR- and cMet-targeted amivantamab; PDL1-targeted avelumab; and PD1-targeted pembrolizumab. Each patient is eligible to receive up to two FT536 treatment cycles, with each cycle consisting of outpatient lympho-conditioning chemotherapy (cyclophosphamide and fludarabine), monoclonal antibody therapy, and three once-weekly doses of FT536.

FT573: iPSC-derived, CAR NK Cell Product Candidate Targeting B7H3

B7H3 (CD276) belongs to the B7 superfamily of immune checkpoint molecules. B7H3 protein is aberrantly overexpressed in a wide variety of cancers, with limited expression at low level in normal tissues, and is often associated with poor prognosis. Recent studies have shown that B7H3 is a critical promoter of tumorigenesis and metastasis, and its expression is a metabolic hallmark of cancer. Multiple modalities targeting B7H3 have shown early clinical activity in patients with advanced solid tumors.

We are developing FT573, a preclinical NK cell product candidate derived from a clonal engineered master iPSC line. FT573 incorporates a B7H3-targeted CAR construct comprised of a single-domain targeting sequence derived from a novel anti-B7H3 camelid antibody. Camelid antibody-derived single-domain fragments are desirable antigen binding strategies as they maintain high target affinity and specificity associated with conventional antibodies, while at the same time demonstrate good physiochemical stability, reduced immunogenicity, and preferred agility associated with their reduced size. In in vitro preclinical studies, we have shown that FT573 cells exhibit antigen-specific cytotoxicity as evidenced by enhanced cytokine release and degranulation.

FT819: iPSC-derived, TCR-KO, TRAC-targeted CAR19 Engineered T-Cell Product Candidate

In addition to our development of iPSC-derived CAR NK cell product candidates, we are also developing CAR T-cell product candidates derived from clonal master engineered iPSC lines as off-the-shelf cancer immunotherapies for the treatment of hematologic malignancies and solid tumors.

In September 2016, we announced a multi-year research partnership with Memorial Sloan Kettering Cancer Center for the development of off-the-shelf engineered T-cell product candidates using clonal master iPSC lines and, in July 2019, we extended the partnership for an additional three years. Research and development activities under the collaboration are being led by Dr. Michel Sadelain, Director of the Center for Cell Engineering and the Stephen and Barbara Friedman Chair at Memorial Sloan Kettering Cancer Center.

In connection with the formation of our research partnership with Memorial Sloan Kettering Cancer Center, we exclusively licensed from Memorial Sloan Kettering foundational intellectual property covering iPSC-derived cellular immunotherapy, including T cells and NK cells derived from iPSCs engineered with CARs, for human therapeutic use. We also secured an option to exclusively license intellectual property arising from all research and development activities under the partnership. In May 2018, we licensed from Memorial Sloan Kettering Cancer Center additional intellectual property covering compositions of novel CAR constructs, including the 1XX CAR construct, and of genetically engineered CAR T cells, including methods of making these cells using CRISPR for certain targeted gene modifications. Embodiments of this additional intellectual property include preclinical data published by Dr. Sadelain demonstrating that directing a CD19-specific CAR to the T-cell receptor (TCR) alpha constant (TRAC) locus results in uniform CAR expression in human peripheral blood T cells, enhances T-cell potency, and delays effector T-cell differentiation and exhaustion, and that CAR T cells utilizing a novel 1XX CAR signaling domain exhibited enhanced antitumor activity, persistence and long-term cytotoxicity as well as a decrease in T-cell exhaustion.

FT819 is an investigational off-the-shelf CAR T-cell cancer immunotherapy derived from a clonal engineered master iPSC line with complete elimination of TCR expression and the novel 1XX CAR targeting CD19 inserted into the TRAC locus. Together, these features are intended to induce antigen-specific cytotoxicity, enhance CAR activity through TRAC-regulated expression and completely eliminate TCR expression to mitigate GvHD.

In preclinical studies, we have shown that FT819 cells:

- display antigen-specific anti-tumor potency *in vitro*, including cytokine release and targeted cellular cytotoxicity, comparable to peripheral blood CD19-specific CAR T-cells;
- do not respond or proliferate against HLA-mismatched (CD19-) peripheral blood mononuclear cells as targets in a mixed lymphocyte reaction, indicating the risk of GvHD is alleviated;
- control tumor progression *in vivo* comparable to peripheral blood CD19-specific CAR T cells in a preclinical mouse model of acute lymphoblastic leukemia; and
- enhance tumor clearance and durable control of leukemia *in vivo*, as compared to primary CAR19 T cells, in a xenograft mouse model of disseminated lymphoblastic leukemia.

We are studying FT819 in an ongoing, multi-center Phase 1 clinical trial designed to assess the safety and determine the maximum dose of FT819 following outpatient lympho-conditioning chemotherapy (cyclophosphamide and fludarabine) in up to 297 adult patients across three types of B-cell leukemias and lymphomas. The trial includes assessment of three treatment regimens, with enrollment to each occurring independently among the three disease types: Regimen A as a single dose of FT819; Regimen B as a single dose of FT819 with IL-2 cytokine support; and Regimen C as three doses of FT819. Enrollment in the dose-escalation stage is currently ongoing.

Initial Proof-of-Concept Clinical Studies

FT500. Our first clinical investigation of an off-the-shelf NK cell cancer immunotherapy derived from a clonal master iPSC line was the conduct of a Phase 1 clinical trial of FT500, which was designed to assess the safety and tolerability of FT500 in adult patients with advanced solid tumors both as a monotherapy and in combination with FDA-approved immune checkpoint inhibitor (ICI) therapies in patients that have failed prior ICI therapy. To our knowledge, FT500 was the first-ever iPSC-derived cell therapy cleared for clinical investigation in the United States. In November 2021, we reported clinical data from the dose-expansion stage of the Phase 1 clinical trial of FT500 as of an October 1, 2021 cutoff date. The Phase 1 dose-expansion treatment schedule consisted of outpatient lympho-conditioning chemotherapy (cyclophosphamide and fludarabine), checkpoint inhibitor therapy, and three once-weekly doses of FT500 each with IL-2 cytokine support. For those patients clinically stable at Day 29, a second treatment cycle, without lympho-conditioning chemotherapy, was available for administration. Ten heavily pre-treated patients with classical Hodgkin lymphoma or non-small cell lung cancer (NSCLC) were administered FT500. No events of any grade of CRS, ICANS, or GvHD, were reported by investigators. Enrollment in the Phase 1 clinical trial of FT500 is closed, and we do not plan to conduct any further development of FT500.

FT516. We also conducted a Phase 1 clinical trial of FT516 to assess its safety and activity in combination with avelumab, an anti-PDL1 checkpoint inhibitor therapy, in adult patients with advanced solid tumors. In November 2021, we reported clinical data from the dose-escalation stage of the Phase 1 clinical trial of FT516 as of an October 1, 2021 cutoff date. The Phase 1 dose-escalation treatment schedule consisted of outpatient lympho-conditioning chemotherapy (cyclophosphamide and fludarabine), avelumab, and three once-weekly doses of FT516 each with IL-2 cytokine support. For those patients clinically stable at Day 29, a second treatment cycle, with lympho-conditioning chemotherapy, was available for administration. Twelve heavily pre-treated patients with advanced solid tumors were administered FT516. No events of any grade of ICANS or GvHD, were reported by investigators. A single case of Grade 1 CRS was reported. Enrollment in the Phase 1 clinical trial of FT516 is closed, and we do not plan to conduct any further development of FT516 in advanced solid tumors.

Our Partnerships

Janssen Biotech

In April 2020, we entered into a collaboration and option agreement with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson, for the development and commercialization of off-the-shelf, iPSC-derived CAR NK cell and CAR T-cell product candidates directed to up to four tumor-associated antigen targets.

We are conducting research and preclinical development of collaboration candidates. We granted to Janssen, during a specified period of time, the right to exercise an exclusive option and obtain an exclusive license under certain intellectual property rights to develop and commercialize each collaboration candidate. Subject to the exercise of such exclusive option, Janssen is solely responsible for the worldwide clinical development and commercialization of such collaboration candidate. Upon attainment of clinical proof-of-concept, we have the right to elect to co-commercialize and share equally in the profits and losses in the United States, subject to sharing in certain development costs, of such collaboration candidate. We are primarily responsible for the manufacture, at Janssen's cost, of collaboration candidates.

Under the terms of the agreement, we received $100.0 million as of the effective date of the agreement, of which $50.0 million was an upfront, non-refundable and non-creditable cash payment and $50.0 million was in the form of an equity investment by Johnson & Johnson Innovation - JJDC, Inc. Additionally, as consideration for our conduct of research, preclinical development and IND-enabling activities for collaboration candidates, Janssen pays us research and development fees as set forth in an annual budget.

We are eligible to receive upon the achievement of specified development, regulatory and sales milestones (i) with respect to the first tumor-associated antigen target, payments of up to $898.0 million for the first collaboration candidate and up to $460.0 million for each additional collaboration candidate; and with respect to each of the second, third and fourth tumor-associated antigen targets, payments of up to $706.0 million for each of the first collaboration candidates and up to $340.0 million for each additional collaboration candidate. Certain milestone payments are subject to reduction in the event we elect to co-commercialize and share equally in the profits and losses in the United States of a collaboration candidate. We are further eligible to receive double-digit tiered royalties ranging up to the mid-teens on net sales of collaboration candidates that are commercialized by Janssen, subject to reduction under certain circumstances.

Janssen may terminate the agreement with respect to one or more tumor-associated antigen targets, or in its entirety, at any time on or after the second anniversary of the effective date of the agreement, and we may terminate the agreement with respect to a particular tumor-associated antigen target if a collaboration candidate has not been selected for IND-enabling studies for such tumor-associated antigen target within specified time periods under certain conditions. The agreement contains customary provisions for termination by either party in the event of a material breach of the agreement, subject to cure, by the other party and in the event of any bankruptcy, insolvency or similar events with respect to the other party.

During 2021, we achieved a pre-defined research milestone associated with a product candidate directed to a first tumor-associated antigen under the Janssen Agreement and received a cash payment of $3.0 million.

Ono Pharmaceutical

In September 2018, we entered into a collaboration and option agreement with Ono Pharmaceutical Co. Ltd. (Ono) for the joint development and commercialization of two off-the-shelf, iPSC-derived CAR T-cell product candidates. The first off-the-shelf, iPSC-derived CAR T-cell candidate (Candidate 1) targets an antigen expressed on certain lymphoblastic leukemias, and the second off-the-shelf, iPSC-derived CAR T-cell candidate (Candidate 2) targets a novel antigen identified by Ono expressed on certain solid tumors (each a Candidate and, collectively, the Candidates). We granted to Ono, during a specified period of time, an option to obtain an exclusive license under certain intellectual property rights to develop and commercialize (a) Candidate 1 in Asia, where we retained rights for development and commercialization in all other territories of the world and (b) Candidate 2 in all territories of the world, where we retain rights to co-develop and co-commercialize Candidate 2 in the United States and Europe under a joint arrangement with Ono under which we are eligible to share at least 50% of the profits and losses. For each Candidate, the option expires upon the earliest of: (a) the achievement of the pre-defined preclinical milestone, (b) termination by Ono of research and development activities for the Candidate and (c) the date that is the later of (i) four years after the effective date and (ii) completion of all applicable activities contemplated under the joint development plan. We maintain worldwide rights of manufacture for Candidates.

Under the terms of the agreement, Ono paid us an upfront, non-refundable and non-creditable payment of $10.0 million in connection with entering into the agreement. Additionally, as consideration for our conduct of research and preclinical development under a joint development plan, Ono pays us annual research and development fees set forth in the annual budget included in the joint development plan, which fees are estimated to be $20.0 million in aggregate over the course of the joint development plan.

In December 2020, we entered into a letter agreement with Ono pursuant to which Ono nominated and delivered to us proprietary antigen binding domains targeting an antigen expressed on certain solid tumors for incorporation into Candidate 2. In connection with such nomination and delivery, Ono paid us a milestone fee of $10.0 million for further research and development of Candidate 2. In addition, Ono terminated further development with respect to Candidate 1, and we retain all rights to research, develop and commercialize Candidate 1 throughout the world without any obligation to Ono.

Ono has agreed to pay us up to an additional $20.0 million, subject to the exercise by Ono of its option to develop and commercialize Candidate 2. Subject to Ono's exercise of the option and to the achievement of certain clinical, regulatory and commercial milestones with respect to Candidate 2 in specified territories, we are entitled to receive an aggregate of up to $885.0 million in milestone payments for Candidate 2, with the applicable milestone payments for the United States and Europe subject to reduction by 50% if we elect to co-develop and co-commercialize Candidate 2 as described above. We are also eligible to receive tiered royalties ranging from the mid-single digits to the low-double digits based on annual net sales by Ono of Candidate 2 in specified territories, with such royalties subject to certain reductions.

The agreement will terminate with respect to a Candidate if Ono does not exercise its option for a Candidate within the option period, or in its entirety if Ono does not exercise any of its options for the Candidates within their respective option periods. In addition, either party may terminate the agreement in the event of breach, insolvency or patent challenges by the other party; provided, that Ono may terminate the agreement in its sole discretion (x) on a Candidate-by-Candidate basis at any time after the second anniversary of the effective date of the agreement or (y) on a Candidate-by-Candidate or country-by-country basis at any time after the expiration of the option period, subject to certain limitations. The agreement will expire on a Candidate-by-Candidate and country-by-country basis upon the expiration of the applicable royalty term, or in its entirety upon the expiration of all applicable payment obligations under the agreement.

Our Intellectual Property

Overview

We seek to protect our product candidates and our cell programming technology through a variety of methods, including seeking and maintaining patents intended to cover our products and compositions, their methods of use and processes for their manufacture, our platform technologies and any other inventions that are commercially important to the development of our business. We seek to obtain domestic and international patent protection and, in addition to filing and prosecuting patent applications in the

United States, we typically file counterpart patent applications in additional countries where we believe such foreign filing is likely to be beneficial, including Europe, Japan, Canada, Australia and China. We continually assess and refine our intellectual property strategy in order to best fortify our position, and file additional patent applications when our intellectual property strategy warrants such filings. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We have entered into exclusive license agreements with various academic and research institutions to obtain the rights to use certain patents for the development and commercialization of our product candidates.

As of February 18, 2022, our intellectual property portfolio is composed of over 400 issued patents and 150 patent applications that we license from academic and research institutions, and over 300 issued patents or pending patent applications that we own. These patents and patent applications generally provide us with the rights to develop our product candidates in the United States and worldwide. This portfolio covers compositions of programmed cellular immunotherapies, our cell programming approach for enhancing the therapeutic function of cells *ex vivo*, and our platform for industrial-scale iPSC generation and engineering. We believe that we have a significant intellectual property position and substantial know-how relating to the programming of hematopoietic and immune cells and to the derivation, genetic engineering, and differentiation of iPSCs.

We cannot be sure that patents will be granted with respect to any of our owned or licensed pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any of our existing patents or any patents we may own or license in the future will be useful in protecting our technology. Please see "Risk Factors—Risks Related to Our Intellectual Property" for additional information on the risks associated with our intellectual property strategy and portfolio.

Intellectual Property Relating to iPSC Technology and Platform

As of February 18, 2022, we own over 20 patent families directed to programming the fate of somatic cells *ex vivo*, including patent applications pending in the U.S. and internationally related to our platform for industrial-scale iPSC generation and applications related to differentiation of iPSCs into specialized cells with therapeutic potential. These patent applications cover our proprietary small molecule-enhanced iPSC platform, including novel reprogramming factors and methods of reprogramming to obtain iPSCs. Our intellectual property portfolio also includes gene editing compositions and methods of genetic engineering, as well as methods of directing the fate of cells to obtain homogenous cell populations in the hematopoietic lineage, including $CD34^+$ cells, T cells and NK cells. Our proprietary intellectual property enables highly-efficient iPSC derivation, selection, engineering, and clonal expansion while maintaining genomic stability. Any U.S. patents issued from these patent applications are expected to have statutory expiration dates ranging from 2031 to 2042.

Additionally, we have licensed from the Whitehead Institute for Biomedical Research a portfolio of four patent families including issued patents and pending applications broadly applicable to the reprogramming of somatic cells. Our license is exclusive in commercial fields, including for drug discovery and therapeutic purposes. This portfolio covers the generation of human iPSCs from somatic cells and, as of February 18, 2022, includes 16 issued U.S. patents (including U.S. Patents 8,071,369, 7,682,828 and 9,497,943) claiming compositions used in the reprogramming of mammalian somatic cells to a less differentiated state (including to a pluripotent state), and methods of making a cell more susceptible to reprogramming. Specifically, the portfolio includes a composition of matter patent issued in the United States covering a cellular composition comprising a somatic cell having an exogenous nucleic acid that encodes an OCT4 protein. OCT4 is the key pluripotency gene most commonly required for the generation of iPSCs. These issued patents and any U.S. patents that may issue from these pending patent applications are expected to have statutory expiration dates ranging from 2024 to 2029.

We also have exclusive licenses from The Scripps Research Institute to a portfolio of seven patent families relating to compositions and methods for reprogramming mammalian somatic cells, which covers non-genetic and viral-free reprogramming mechanisms, including the use of various small molecule classes and compounds and the introduction of cell-penetrating proteins to reprogram mammalian somatic cells. This portfolio includes issued U.S. patents (including U.S. Patents 8,044,201 and 8,691,573) that provide composition of matter protection for a class of small molecules, including thiazovivin, that is critical for inducing the generation, and maintaining the pluripotency, of iPSCs, and compositions and methods of using the small molecule. Any issued U.S. patents and any U.S. patents that may issue from patent applications pending in this portfolio are expected to have statutory expiration dates ranging from 2026 to 2031.

We also have exclusively licensed from the J. David Gladstone Institutes (Gladstone) intellectual property covering the generation of iPSCs using CRISPR-mediated gene activation. This approach for inducing pluripotency uses CRISPR to directly target a specific location of the genome and activate endogenous gene expression, and does not rely on established methods of cellular reprogramming that require the transduction of multiple transcription factors. Any U.S. patents that may issue from patent applications pending in the U.S. and internationally in this portfolio are expected to have a statutory expiration date in 2038.

We also have licensed exclusive rights to four families of patent applications from the University of Minnesota. As of February 18, 2022 this portfolio includes over 70 issued patents or pending patent applications in the United States and foreign jurisdictions directed to compositions of NK cells, including adaptive memory NK cells and genetically-engineered NK cells, and therapeutic

strategies for the treatment of cancer using these NK cells. These applications also describe methods of enhancing NK cell cytotoxicity by genetically engineering the CD16 Fc receptor in immune cells, including iPSC-derived NK cells, and describe methods of increasing NK cell tumor specificity and cytotoxicity by incorporating CARs on NK cells. Any U.S. patents that may issue from patent applications pending in this portfolio are expected to have statutory expiration dates between 2035 and 2038.

We also have exclusively licensed from The Memorial Sloan-Kettering Cancer Center (MSK) intellectual property covering the production and composition of iPSC-derived T cells and their use in cellular immunotherapy, and have a license from MSK to two patent families covering novel CAR constructs as well as off-the-shelf CAR T cells, including the use of CRISPR and other innovative technologies for their production. Collectively, this portfolio covers compositions of CAR constructs, compositions of T cells and NK cells derived from pluripotent cells which are engineered with CARs, methods of engineering pluripotent cell lines, methods of deriving CAR-T cells from CAR expressing pluripotent stem cells, and methods of using CRISPR for producing off-the-shelf T-cell immunotherapies. Any U.S. patents that may issue from patent applications pending in this portfolio are expected to have statutory expiration dates between 2034 and 2038.

In addition, we have licensed exclusive rights from the Max Delbruck Center for Molecular Medicine (MDC) to intellectual property directed to novel humanized antibody fragments, antigen-binding domains and CAR constructs that uniquely target and specifically bind B-cell Maturation Antigen (BCMA). Under the license agreement, we are granted an exclusive license for use in allogeneic engineered pluripotent stem cells. Any patents issuing from patent applications pending in the U.S. and internationally in this portfolio are expected to have statutory expiration dates between 2033 and 2037.

We have also licensed exclusive rights from the Dana-Farber Cancer Institute to certain intellectual property covering novel antibody fragments that uniquely and specifically bind the alpha-3 domain of MICA/B. We are granted exclusive worldwide rights for use in iPSC-derived cellular therapeutics for the treatment of human disease under the license agreement. Any patents that may issue from patent applications pending in this portfolio are expected to have statutory expiration dates in 2038.

Intellectual Property Relating to CRISPR Engineering

In August 2019, we entered into a license agreement with Inscripta, Inc. Under the license agreement, we obtained a royalty-free, irrevocable license to a patent portfolio covering the composition, production and use of MAD7, a novel gene-editing CRISPR endonuclease from the *Eubacterium rectale* genome. The intellectual property includes issued patents and pending applications broadly applicable to MAD7 and the editing of mammalian cells. Our license covers the making and using of MAD7 for editing iPSCs, making master engineered iPSC lines and using master engineered iPSC lines to manufacture human therapeutic products. We expect U.S. patents related to this work to have statutory expiration dates starting in 2037.

Intellectual Property Relating to the Programming of Hematopoietic Cells

As of February 18, 2022, we own 16 families of U.S. and foreign patents and pending patent applications covering our cell programming technology and compositions of programmed cellular immunotherapies. This portfolio includes over 150 issued patents or pending patent applications relating to methods of programming the biological properties and therapeutic function of cells *ex vivo*, and the resulting therapeutic compositions of hematopoietic and immune cells. Patents and patent applications in this portfolio include claims covering (i) therapeutic compositions of hematopoietic and immune cells, including T cells, NK cells, and $CD34^+$ cells, that have been programmed *ex vivo* with one or more agents to optimize their therapeutic function for application in oncology and immune disorders and (ii) methods of programming cells including by the activation or inhibition of therapeutically-relevant genes and cell-surface proteins, such as those involved in the homing, proliferation and survival of hematopoietic cells or those involved in the persistence, proliferation and reactivity of immune cells. Any U.S. patents within this portfolio that have issued or may yet issue from pending patent applications will have statutory expiration dates between 2030 and 2042.

Our Material Technology License Agreements

The University of Minnesota

In December 2016, we entered into a license agreement with the Regents of the University of Minnesota for rights relating to compositions and methods relating to NK cells, to modifications of cytotoxic receptors naturally expressed on NK cells including the CD16 Fc receptor, and to CARs for expression on NK cells. Under our agreement with the University of Minnesota, we acquired an exclusive royalty-bearing, sublicensable, worldwide license to make, use and sell licensed products in all fields for commercial purposes. The licensed patent rights are described in more detail above under “Intellectual Property Relating to the Programming of Hematopoietic Cells.” The University of Minnesota retains the right to practice the patent rights for research, teaching and educational purposes, including in corporate-sponsored research subject to certain limitations during the initial three years of the license agreement. The University of Minnesota also retains the right to license other academic and non-profit research institutes to practice

the patent rights for research, teaching and educational purposes, but not for corporate-sponsored research. Our license is also subject to pre-existing rights of the U.S. government.

Under the terms of the license agreement, we are required to pay the University of Minnesota an annual license maintenance fee during the term of the agreement, and are also required to make payments of up to $4.6 million for development, regulatory and commercial milestones achieved with respect to each of the first three licensed products. If commercial sales of a licensed product commence, we will also be required to pay royalties at percentage rates in the low-single digits on net sales of licensed products. Our royalty payments are subject to reduction for any third-party payments required to be made until a minimum royalty percentage has been reached. In the event that we sublicense the patent rights, the University of Minnesota is also entitled to receive a percentage of the sublicensing income received by us.

Under the license agreement with the University of Minnesota, we are obligated to use commercially reasonable efforts to develop and make commercially available licensed products. In particular, we are required to conduct activities toward specific development milestones of licensed products on an annual basis.

The agreement will continue until the abandonment of all patent rights or expiration of the last to expire licensed patent. The University of Minnesota may terminate the agreement if we default in the performance of any of our obligations and fail to cure the default within a specified grace period. The University of Minnesota may also terminate the agreement if we cease to carry out our business or become bankrupt or insolvent. We may terminate the agreement for any reason upon prior written notice to the University of Minnesota and payment of all amounts due to the University of Minnesota through the date of termination.

Memorial Sloan Kettering Cancer Center

In May 2018, we entered into an amended and restated license agreement with Memorial Sloan Kettering Cancer Center. The agreement amends and restates the exclusive license agreement we entered into with Memorial Sloan Kettering Cancer Center in August 2016, under which we obtained rights relating to compositions and methods covering iPSC-derived cellular immunotherapy, including T cells and NK cells derived from iPSCs engineered with CARs. Pursuant to the amended and restated license agreement, we continue to hold exclusive rights to the foregoing patents and patent applications, and obtained additional licenses to certain patents and patent applications relating to compositions and methods covering novel CAR constructs as well as off-the-shelf CAR T cells, including the use of CRISPR and other innovative technologies for their production.

Under our amended and restated agreement with Memorial Sloan Kettering Cancer Center, we have royalty-bearing worldwide licenses to make, use and sell licensed products in all fields for human therapeutic uses. The licensed patent rights are described in more detail above under “Intellectual Property Relating to iPSC Technology.” For those patent families where our rights are exclusive, Memorial Sloan Kettering Cancer Center retains the right to practice the patent rights for research, teaching and non-clinical research purposes, and to license other academic and non-profit research institutes to practice the patent rights for research, teaching and non-clinical research purposes. Our licenses are also subject to pre-existing rights of the U.S. government.

Under the terms of the amended and restated agreement, we are required to pay Memorial Sloan Kettering Cancer Center an annual license maintenance fee during the term of the agreement, and are also required to make payments of up to $12.5 million for development, regulatory and commercial milestones achieved with respect to each licensed products. If commercial sales of a licensed product commence, we will also be required to pay royalties at percentage rates up to the high-single digits on net sales of licensed products. Our royalty payments are subject to reduction for any third-party payments required to be made until a minimum royalty percentage has been reached. In the event that we sublicense the patent rights, Memorial Sloan Kettering Cancer Center is also entitled to receive a percentage of the sublicensing income received by us. Additionally, in the event a licensed product achieves a specified clinical milestone, Memorial Sloan Kettering Cancer Center is then eligible to receive additional milestone payments, where the amount of such payments owed to Memorial Sloan Kettering Cancer Center are contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone.

Under the amended and restated agreement with Memorial Sloan Kettering Cancer Center, we are obligated to use commercially reasonable efforts to develop and make commercially available licensed products. In particular, we are required to conduct activities and commit a minimum amount of funding toward specific development milestones of licensed products on an annual basis.

The agreement will continue until the abandonment of all patent rights or expiration of the last to expire licensed patent. Memorial Sloan Kettering Cancer Center may terminate the agreement if we default in the performance of any of our obligations and fail to cure the default within a specified grace period, if we cease to carry out our business or become bankrupt or insolvent, or if we institute a proceeding to challenge the patent rights. We may terminate the agreement for any reason upon prior written notice to Memorial Sloan Kettering Cancer Center.

Max Delbruck Center

In December 2018, we entered into a license agreement with Max Delbruck Center for Molecular Medicine (MDC) for rights relating to novel humanized antibody fragments, antigen-binding domains and CAR constructs that uniquely target and specifically bind B-cell Maturation Antigen (BCMA). Under our license agreement with MDC, we acquired an exclusive royalty-bearing, sublicensable, worldwide license to make, use and sell products covered by the licensed patent rights, and to perform licensed processes, in each case, using cells derived from allogeneic engineered stem cells. MDC retains a non-exclusive right to use the technology for its own internal research, teaching, and educational purposes.

Under the terms of the license agreement, we are required to pay to MDC an annual license maintenance fee during the term of the agreement. We also are required to make product development, regulatory and sales milestones payments to MDC of up to $11 million per product. If commercial sales of a licensed product commence, we will pay MDC royalties at percentage rates ranging in the low single digits on net sales of licensed products in countries where such product is protected by patent rights. Our obligation to pay royalties continues on a country-by-country basis until the expiration of all licensed patent rights covering licensed products in such country, and our royalty payments will be reduced by other payments we are required to make to third parties in certain circumstances until a minimum royalty percentage has been reached. In the event that we sublicense the patent rights, MDC is also entitled to receive a percentage of the sublicensing income received by us.

Under the license with MDC, we are obligated to use commercially reasonable efforts to develop and obtain approval of a licensed product.

The agreement will expire concurrently with patent rights on a country-by-country basis. We may terminate the agreement by providing prior written notice to MDC, and MDC has the right to terminate the agreement if we materially breach the agreement and fail to cure such breach within a specified grace period.

Whitehead Institute for Biomedical Research

In February 2009, we entered into a license agreement with the Whitehead Institute for Biomedical Research, as amended in October 2009 and September 2010, for rights relating to compositions and methods for reprogramming somatic cells to a less differentiated or pluripotent state. Under our agreement with the Whitehead Institute, we acquired an exclusive royalty-bearing, sublicensable, worldwide license to make, use and sell licensed products in all fields for commercial purposes, excluding the sale or distribution of reagents for basic research use. The licensed patent rights are described in more detail above under “Intellectual Property Relating to iPSC Technology.” The Whitehead Institute retains the right to practice the patent rights for research, teaching and educational purposes, including in corporate-sponsored research under limited circumstances and in some cases only after obtaining our consent. The Whitehead Institute also retains the right to license other academic and non-profit research institutes to practice the patent rights for research, teaching and educational purposes, but not for corporate-sponsored research. Our license is also subject to pre-existing rights of the U.S. government.

Under the terms of the license agreement, we are required to pay the Whitehead Institute an annual license maintenance fee during the term of the agreement, and are also required to make payments of up to $2.3 million for development and regulatory milestones achieved with respect to licensed products. If commercial sales of a licensed product commence, we will also be required to pay royalties at percentage rates in the low-single digits on net sales of licensed products. Our royalty payments are subject to reduction for any third-party payments required to be made until a minimum royalty percentage has been reached. In the event that we sublicense the patent rights, the Whitehead Institute is also entitled to receive a percentage of the sublicensing income received by us.

Under the license agreement with the Whitehead Institute, we are obligated to use commercially reasonable efforts to develop and commercialize licensed products, and to make licensed products or processes reasonably available to the public. In particular, we are required to commit a minimum amount of funding toward the development of a licensed product on an annual basis or conduct activities toward specific development milestones.

The agreement will continue until the abandonment of all patent rights or expiration of the last to expire licensed patent. The Whitehead Institute may terminate the agreement if we default in the performance of any of our obligations and fail to cure the default within a specified grace period, or if we institute a proceeding to challenge the patent rights. The Whitehead Institute may also terminate the agreement if we cease to carry out our business or become bankrupt or insolvent. We may terminate the agreement for any reason upon prior written notice to the Whitehead Institute and payment of all amounts due to the Whitehead Institute through the date of termination.

The Scripps Research Institute

We have entered into various license agreements with The Scripps Research Institute (TSRI) for rights relating to compositions and methods for reprogramming somatic cells, including the use of various small molecule classes and compounds in the reprogramming and maintenance of iPSCs. Under our agreements with TSRI (the TSRI License Agreements), we acquired exclusive royalty-bearing, sublicensable, worldwide licenses to make, use and sell products covered by the licensed patent rights, and to perform licensed processes, in each case, in all fields. The licensed patent rights are described in more detail above under "Intellectual Property Relating to iPSC Technology." TSRI retains a non-exclusive right to practice and use the patent rights for non-commercial educational and research purposes, and to license other academic and non-profit research institutions to practice the patent rights for internal basic research and education purposes. Under certain of our TSRI License Agreements, other third parties maintain a right to practice the patent rights for their internal use only. Our license is also subject to pre-existing rights of the U.S. government.

Under the terms of the TSRI License Agreements, we are required to pay to TSRI annual minimum fees during the term of each agreement. Additionally, upon the achievement of specific regulatory and commercial milestones, we are required to make payments to TSRI of up to approximately $1.8 million under each of the TSRI License Agreements. We will also be required to pay TSRI royalties at percentage rates ranging in the low- to mid-single digits on net sales of licensed products. In the event that we sublicense the patent rights, TSRI is also entitled to receive a percentage of the sublicensing income received by us.

Under the TSRI License Agreements, we are obligated to use commercially reasonable efforts to meet the development benchmarks set out in development plans under each of the TSRI License Agreements, or otherwise expend a minimum specified amount per year for product development. TSRI has the right to terminate any TSRI License Agreement if we fail to perform our obligations under the applicable agreement, including failure to meet any development benchmark or to use commercially reasonable efforts and due diligence to develop a licensed product, or if we otherwise breach the agreement, challenge the licensed patent rights, are convicted of a felony involving the development or commercialization of a licensed product or process, or become insolvent. We may terminate any of our TSRI License Agreements by providing ninety days' written notice to TSRI. Each TSRI License Agreement otherwise terminates upon the termination of royalty obligations under such agreement.

Dana-Farber Cancer Institute

In April 2020, we entered into a license agreement with the Dana-Farber Cancer Institute (DFCI) for rights relating to novel antibody fragments that uniquely and specifically bind the alpha-3 domain of MICA/B. Under our license agreement with DFCI, we acquired an exclusive royalty-bearing, sublicensable, worldwide license to make, use and sell products covered by the licensed patent rights in the field of iPSC-derived cellular therapeutics for the treatment of human disease, and a non-exclusive royalty-bearing, sublicensable, worldwide license to make, use and sell products covered by the licensed patent rights in the field of cellular therapeutics for the treatment of human disease. DFCI retains the right to practice and to license to other academic, government and non-profit institutes to practice the patent rights for research, teaching and education purposes, as well as to license third parties to practice the patents rights to make or sell research reagents or other research tools solely for use in research. Our licenses are also subject to pre-existing rights of the U.S. government.

Under the terms of the license agreement, we are required to make minimum annual payments to DFCI throughout the term of the agreement. We also are required to make development, commercialization and sales milestones payments to DFCI of up to $25 million per licensed product. If commercial sales of a licensed product commence, we will pay DFCI royalties at percentage rates ranging in the low single digits on net sales of licensed products in countries where such product is protected by licensed patent rights. Our obligation to pay royalties continues on a country-by-country basis until the expiration of all licensed patent rights covering licensed products in such country, and our royalty payments will be reduced by other payments we are required to make to third parties in certain circumstances until a minimum royalty percentage has been reached. In the event that we sublicense the patent rights, DFCI is also entitled to receive a percentage of the sublicensing income received by us.

Under our agreement with DFCI, we are obligated to use reasonable efforts to develop and bring one or more licensed products to the marketplace through a program of development, production and distribution, including by meeting certain diligence benchmarks with respect to exclusively licensed products.

The agreement will continue until the expiration of the last to expire licensed patent. DFCI may terminate the agreement for cause, including if we default in the performance of any of our obligations and fail to cure the default within a specified grace period, if an officer of ours (or of an affiliate or sublicensee) is convicted of a felony related to the manufacture, use, sale or important or a licensed product, if we cease to carry out our business or become bankrupt or insolvent, and if we institute a proceeding to challenge the patent rights. DFCI may also terminate our exclusive license if we fail to materially comply with our diligence obligations. We may terminate the agreement for any reason in its entirety or on a product-by-product or country-by-country basis upon prior written notice to DFCI and payment of all amounts due to DFCI through the date of termination.

Manufacturing

Off-the-shelf, iPSC-derived Cellular Immunotherapies

The manufacture of our off-the-shelf, iPSC-derived cellular immunotherapy product candidates involves a three-stage process:

- The first stage is intended to generate a clonal master iPSC line and generally consists of the following steps: (i) obtain appropriately-consented healthy human donor cells, such as fibroblasts or hematopoietic cells, and conduct transfusion transmissible disease testing on the donor cells; (ii) induction of pluripotency in the donor cells using a proprietary transgene integration-free and footprint-free method of reprogramming; (iii) genetic engineering, where applicable, of iPSCs; and (iv) isolation and selection of a single iPSC, followed by clonal expansion of the single iPSC to produce a clonal master iPSC line for cell product manufacture.
- The second stage is intended to derive the cell product population of interest and generally consists of the following steps: (i) expansion and differentiation of the clonal master iPSC line to produce $CD34^+$ definitive hematopoietic progenitor cells; and (ii) further expansion and differentiation of these progenitor cells to produce the cell product population of interest.
- The third stage is intended to derive the final cell product and generally consists of the following steps: (i) washing the cell product population; (ii) formulating the cell product population in an infusion media for intravenous administration of the final cell product; and (iii) cryopreserving individual aliquots of the final cell product and storing these aliquots in single-dose infusion bags.

As part of our manufacturing process, we endeavor to utilize current Good Manufacturing Process (cGMP) grade materials and reagents, if commercially available; however, certain critical materials and reagents are currently qualified for research use only. Additionally, we obtain key components required for the manufacture of our iPSC-derived cell product candidates from third-party manufacturers and suppliers, which include, in some instances, sole source manufacturers and suppliers. We do not currently have long-term commitments or supply agreements in place to obtain certain key components used in the manufacture of our iPSC-derived cell product candidates.

We are manufacturing our iPSC-derived cell product candidates for use in research, preclinical development, and clinical development. In September 2019, we opened our first cGMP compliant manufacturing facility for the clinical production of our iPSC-derived cell product candidates. This cGMP facility, located in San Diego, California, is custom designed for the manufacture of off-the-shelf cell product candidates using clonal master iPSC lines as the starting cell source. The state-of-the-art facility has been commissioned and qualified, and we have been issued a drug manufacturing license by the State of California, Department of Health Services, Food and Drug Branch. In January 2020, we entered into a new lease agreement for office, laboratory, and manufacturing space (the Premises), which is also designed to include cGMP manufacturing. The Premises are located in San Diego, California and we moved our corporate headquarters to the Premises in August 2021. We intend to extend the manufacture of our iPSC-derived cell product candidates to this facility starting in 2022.

We also contract with third parties, including medical center cell therapy facilities and contract manufacturing organizations (CMOs), for the conduct of some or all of the activities required for manufacturing our iPSC-derived cell product candidates for use in clinical investigation. We expect that we will continue to contract with third parties, including medical center cell therapy facilities and CMOs, for the conduct of some or all of the activities required for manufacturing our iPSC-derived cell product candidates.

Marketing, Market Access, & Sales

We currently intend to commercialize any products that we may successfully develop. We currently have no experience in marketing, market access or selling therapeutic products. We may need to further evaluate and generate evidence beyond what is generated in our clinical program that would satisfy the needs of payers and healthcare technology assessment (HTA) bodies. To market any of our products independently would also require us to develop a sales force with technical expertise along with establishing commercial infrastructure and capabilities. Our commercial strategy for marketing our product candidates also may include the use of strategic partners, distributors, a contract sales force or the establishment of our own commercial infrastructure. We plan to further evaluate these alternatives as we approach approval for the first of our product candidates.

Government Regulation

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act (the FDCA) and the Public Health Service Act (the PHS Act) and related regulations, and drugs under the FDCA and related regulations. Biological products and drugs are also subject to other federal, state, local, and foreign statutes and regulations. The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of biological products and drugs. These agencies and other federal, state, local, and foreign entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, packaging, labeling, storage, distribution, record keeping, reporting, approval or licensing, advertising and promotion, and import and export of our products. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process or after approval may subject an applicant to administrative or judicial sanctions. FDA sanctions include refusal to approve pending applications, withdrawal of an approval or suspension or revocation of a license, clinical hold, warning or untitled letters, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. In addition, government regulation may delay or prevent marketing of product candidates for a considerable period of time and impose costly procedures upon our activities.

Marketing Approval

The process required by the FDA before biological products and drugs may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory and animal tests 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 must become effective before human clinical trials may begin;
- approval of the protocol and related documentation by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before each trial may be initiated;
- 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 subjects and their health information, to establish the safety and efficacy of the proposed biological product or drug for its intended use or uses;
- for a biological product, submission to the FDA of a Biologics License Application (BLA) for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials, and, for a drug, submission of a New Drug Application (NDA) that includes substantive evidence of the product's safety and efficacy;
- satisfactory completion of an FDA pre-approval inspection of manufacturing facilities where the product is produced to assess compliance with the FDA's cGMPs to assure that the facilities, methods and controls are adequate, and, if applicable, current good tissue practices (cGTPs) for the use of human cellular and tissue products to prevent the introduction, transmission or spread of communicable diseases;
- potential FDA audit of the nonclinical study sites and clinical trial sites that generated the data in support of the BLA or NDA;
- review of the product candidate by an FDA advisory committee, where appropriate if applicable;
- payment of user fees for FDA review of the BLA or NDA (unless fee waiver applies); and
- FDA review and approval, or licensure, of the BLA and review and approval of the NDA which must occur before a biological product and a drug can be marketed or sold.

U.S. Biological Products and Drug Development Process

Before testing any biological product or drug candidate in humans, nonclinical tests, including laboratory evaluations and animal studies to assess the potential safety and activity of the product candidate, are conducted. The conduct of the nonclinical tests must comply with federal regulations and requirements including GLPs.

Prior to commencing the first clinical trial, the trial sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of an initial IND application. Some nonclinical testing may continue even after the IND application is submitted. The IND application

automatically becomes effective 30 days after receipt by the FDA unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial and places the trial on a clinical hold. In such case, the sponsor of the IND application must resolve any outstanding concerns with the FDA before the clinical trial may begin. The FDA also may impose a clinical hold on ongoing clinical trials due to safety concerns or non-compliance. If a clinical hold is imposed, a trial may not recommence without FDA authorization and then only under terms authorized by the FDA. A clinical hold may either be a full clinical hold or a partial clinical hold that would limit a trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. An IRB is charged with protecting the welfare and rights of study subjects 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 trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the trial and may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally 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 rules that assure a clinical trial will be stopped if certain adverse events occur. Each protocol and any amendments to the protocol must be submitted to the FDA and to the IRB. Information about certain clinical studies must be submitted with specific timeframes to the National Institutes of Health for public dissemination at www.clinicaltrials.gov.

For purposes of BLA or NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap:

- Phase 1—The investigational product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. These trials may also provide early evidence on effectiveness.
- Phase 2—These trials are conducted in a limited number of patients in the target 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 and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—Phase 3 trials are undertaken to provide statistically significant evidence of clinical efficacy and to further evaluate dosage, potency, and safety in an expanded patient population at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the product has been obtained, and are intended to establish the overall benefit-risk relationship of the investigational product, and to provide an adequate basis for product approval and physician labeling.
- Phase 4 – In some cases, the FDA may condition approval of a BLA or NDA for a product candidate on the sponsor's agreement to conduct additional clinical studies to further assess the drug's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. The FDA has statutory authority to require post-market clinical trials to address safety issues. A sponsor may also voluntarily conduct additional clinical studies after approval to gain more information about their product. All of these trials must be conducted in accordance with GCP requirements in order for the data to be considered reliable for regulatory purposes.

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. Within 15 calendar days after the sponsor determines that the information qualifies for reporting, written IND safety reports must be 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 subjects; 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 also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Regulatory authorities, a data safety monitoring board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB's requirements or if

the investigated product has been associated with unexpected serious harm to patients, and the trial may not recommence without the IRB's authorization.

Typically, if a product is intended to treat a chronic disease, safety and efficacy data must be gathered over an extended period of time, which can range from six months to three years or more.

Concurrently with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the investigational product and 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 the use of biological products, the PHS Act 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. 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.

A drug being studied in clinical trials may be made available to individual patients in certain circumstances. Pursuant to the 21st Century Cures Act (the Cures Act), as amended, the manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational drug, or as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or RMAT. Further, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (the Right to Try Act) among other things, provides a federal framework for certain patients to request access to certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act. We review each individual request for access through the Cures Act, the Right to Try Act and similar state laws, and may or may not provide access depending upon the facts of each request.

U.S. Review and Approval Processes

In order to obtain approval to market a biological product in the United States, a BLA must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety, purity and potency of the investigational product for the proposed indication. Similarly, for a drug, an NDA must be submitted to the FDA that provides data demonstrating the drug is safe and effective. Both a BLA and an NDA include all data available from nonclinical studies and clinical trials, together with detailed information relating to the product's manufacture and composition, and proposed labeling.

Under the Prescription Drug User Fee Act (PDUFA), as amended, each BLA and NDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through September 30, 2022, the user fee for an application requiring clinical data, such as a BLA and an NDA, is $3,117,218. PDUFA also imposes an annual prescription drug product program fee for biologics and drugs ($369,413). 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 having fewer than 500 employees. Additionally, no user fees are assessed on BLAs or NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has 60 days from its receipt of a BLA or NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. The FDA may refuse to file any BLA or NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA or NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. After the BLA or NDA submission is accepted for filing, the FDA reviews the BLA or NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMPs to assure and preserve the product's identity, safety, strength, quality, potency, and purity, and for a biological product, whether it meets the biological product standards. The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically comprised of clinicians and other experts, for evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA or NDA, 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 a human cellular or tissue product, the FDA also will not approve the product if the manufacturer is not in compliance with cGTPs. FDA regulations also require tissue establishments to register and list their human cells, tissues, and cellular and tissue based products (HCT/Ps) with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA or NDA, the FDA may inspect clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCPs. If the FDA determines the manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often

will require the facility to take corrective action and provide documentation evidencing the implementation of such corrective action, which may delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCPs, the FDA may determine the data generated by the site should be excluded from the primary efficacy analyses provided in the BLA or NDA, and request additional testing or data. Additionally, the FDA ultimately may still decide that the application does not satisfy the regulatory criteria for approval.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a biological product or drug outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the BLA or NDA submission. The need for a REMS is determined as part of the review of the BLA or NDA. Based on statutory standards, elements of a REMS may include “dear doctor letters,” a medication guide, more elaborate targeted educational programs, and in some cases restrictions on distribution. These elements are negotiated as part of the BLA or NDA approval, and in some cases may delay the approval date. Once adopted, REMS are subject to periodic assessment and modification.

After the FDA completes its initial review of a BLA or NDA, it will communicate to the sponsor that the biological product will either be approved, or it will issue a complete response letter to communicate that the BLA or NDA will not be approved in its current form. The complete response letter usually describes all of the specific deficiencies in the BLA or NDA 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 or NDA to address all of the deficiencies identified in the letter, or withdraw the application, or request a hearing.

One of the performance goals of the FDA under PDUFA is to review 90% of standard BLAs and NDAs in 10 months and 90% of priority BLAs and NDAs in six months, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and NDAs and its review goals are subject to change from time to time. The review process and the PDUFA goal data may be extended by three months if the FDA requests or the BLA or NDA applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or the indications for use may otherwise be limited. 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 Phase 4 post-marketing clinical trials and testing and surveillance programs to monitor the safety of approved products that have been commercialized. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in the imposition of new restrictions on the product or complete withdrawal of the product from the market.

Post-Approval Requirements

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to monitoring, record-keeping, advertising and promotion, reporting of adverse experiences, and limitations on industry-sponsored scientific and educational activities. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or NDA or a BLA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

FDA regulations require that approved products be manufactured in specific approved facilities and in accordance with cGMP regulations which 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 drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic announced and unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other regulatory requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA does not regulate behavior of physicians in their choice of treatments and physicians may legally prescribe available products for uses that are not described in the product’s labeling and that differ from those approved by the FDA. However, the FDA does restrict an applicant’s communications on the subject of off-label use of their products. The FDA and other agencies actively enforce the laws prohibiting the marketing and promotion of off-label uses, and a company that is found to have improperly marketed or promoted off-label use

may be subject to significant liability, including criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, and mandatory compliance programs.

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, restrictions on a product, and judicial or administrative enforcement.

Expedited Development and Review Programs

The FDA is authorized to designate certain products for expedited review if they demonstrate the potential to address an unmet medical need in the treatment of a serious or life-threatening disease or condition for which there is no effective treatment. These programs are referred to as fast track designation, priority review, accelerated approval, breakthrough therapy designation, and regenerative advanced therapy designation.

Fast Track Designation. The FDA may grant "fast track" status to product candidates that are intended to treat serious or life-threatening diseases or conditions and demonstrate the potential to address an unmet medical need for the condition. Fast track is a process designed to facilitate the development and expedite the review of such product candidates by providing, among other things, more frequent meetings with the FDA to discuss the product candidate's development plan and rolling review, which allows submission of individually completed sections of an NDA or BLA for FDA review before the entire submission is completed. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a product candidate may request the FDA to designate the product as a fast track product at any time during clinical development. Fast track status does not ensure that a product will be developed more quickly or receive FDA approval. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process, or if the designated drug development program is no longer being pursued.

Priority Review. The FDA may give a priority review designation to a product candidate if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or to provide a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. Priority review is intended to reduce the time it takes for the FDA to review a BLA, with the goal to take action on the application within six months from when the application is filed, compared to ten months for a standard review. The FDA will attempt to direct additional resources to the evaluation of an application for a biological product or drug designated for priority review in an effort to facilitate the review.

Accelerated Approval. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect 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 biological product or drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products being considered for accelerated approval.

Breakthrough Therapy Designation. A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation if preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. If so designated, the FDA will expedite the development and review of the product candidate's marketing application, including by meeting with, and providing advice to, the sponsor throughout the product candidate's development, and taking steps to facilitate an efficient review of the development program and to ensure that the design of the clinical trials is as efficient as practicable.

RMAT Designation. As part of the Cures Act, Congress amended the FDCA to create an accelerated approval program for regenerative advanced therapies. To qualify for this program, and be granted regenerative advanced medicine therapy (RMAT) designation, a product must be a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or a combination of such products, and not a product solely regulated as a human cell and tissue product. This program is intended to facilitate efficient development and expedite review of regenerative advanced therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that the product candidate has the potential to address an unmet need for such disease or condition. A BLA for a product candidate that has received RMAT designation may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A

designated RMAT product candidate that is granted accelerated approval and is subject to post approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post approval monitoring of all patients treated with such therapy prior to its approval.

Fast Track designation, priority review, accelerated approval, breakthrough therapy designation, and RMAT designation do not change the standards for approval but may expedite the development or approval process. Moreover, even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

U.S. Patent Term Restoration and Marketing Exclusivity

Under certain circumstances, U.S. patents 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 Amendments. Patent term restoration can compensate for time lost during product development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. 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 period of patent term restoration is generally one-half the time between the effective date of an IND application (falling after issuance of the patent) and the submission date of a BLA or NDA, plus the time between the submission date of the BLA or NDA and the approval of that application, provided the sponsor acted with diligence. 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 application for patent term extension is subject to approval by the U.S. Patent and Trademark Office in consultation with the FDA. A patent term extension is only available when the FDA approves a biological product or drug for the first time.

With the Hatch-Waxman Amendments, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the FDCA. To obtain approval of a generic drug, an applicant must submit to the agency an abbreviated new drug application (ANDA) which relies on the preclinical and clinical testing previously conducted for a drug approved under an NDA, known as the reference listed drug (RLD). For the ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. The FDA must also determine that the generic drug is bioequivalent to the innovator drug.

An abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, which was part of the Patient Protection and Affordable Care Act of 2010 (ACA). This amendment to the PHS Act attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a biological product is biosimilar to the reference biological product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the product and the reference product may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product.

A reference biological product is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biological product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologic's patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

A biological product or drug can obtain pediatric market exclusivity in the United States. 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 study in accordance with an FDA-issued "Written Request" for such a study.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to biological products and drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a biological product or drug in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting a BLA or NDA. After the FDA grants orphan drug designation, the identity of the applicant, the name of the therapeutic agent and its designated 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 biological product or drug that receives orphan drug designation is the first such product approved by FDA for the orphan indication, it receives orphan product exclusivity, which for seven years prohibits the FDA from approving another application to market the same product for the same indication. Orphan product exclusivity will not bar approval of another product under certain circumstances, including if the new product is shown to be clinically superior to the approved product on the basis of greater efficacy or safety or a demonstration that the new product otherwise makes a major contribution to patient care. More than one product may also be approved by the FDA for the same orphan indication or disease as long as the products are different. If a biological product or drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar, but not identical, benefits.

Pediatric Research Equity Act

Under the Pediatric Research Equity Act (PREA), as amended, a BLA or NDA or supplement must contain data to assess the safety and effectiveness of the biological product or drug 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 intent of PREA is to compel sponsors whose products have pediatric applicability to study those products in pediatric populations. The FDCA requires manufacturers of biological products and drugs that include a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to submit a pediatric study plan to the FDA as part of the IND application. The plan must be submitted not later than 60 days after the end-of-Phase 2 meeting with the FDA; or if there is no such meeting, before the initiation of any Phase 3 trials or a combined Phase 2 and Phase 3 trial; or if no such trial will be conducted, no later than 210 days before submitting a marketing application or supplement. The FDA may grant deferrals for submission of data or full or partial waivers. Generally, PREA does not apply to any biological product or drug for an indication for which orphan designation has been granted.

Coverage and Reimbursement

Sales of our products, when and if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States, no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. Additionally, coverage determinations often require generating additional evidence related, for example, to the relative costs and benefits of new therapies versus standard of care – which goes beyond the data able to be generated within our clinical programs.

In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, which decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, coverage determination is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of biosimilars for branded prescription drugs. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement.

Healthcare Reform and Other Regulatory Changes

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended, collectively known as the ACA was enacted in the United States. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. The ACA contained a number of provisions, including those governing enrollment in federal

healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are that the ACA:

- subjects biological products to potential competition by biosimilars;
- made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs to 23.1% of average manufacturer price (AMP), and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP;
- imposed a requirement on manufacturers of branded drugs to provide a 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discount off the negotiated price of branded drugs dispensed to Medicare Part D beneficiaries in the coverage gap (i.e., "donut hole") as a condition for a manufacturer's outpatient drugs being covered under Medicare Part D; and
- extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations.

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

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted:

- On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional action is taken by Congress. 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, 2022 due to the COVID-19 pandemic. Then, a 1% payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022.
- On January 2, 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.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

At the federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021 CMS rescinded the Most Favored Nations rule. Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

At the state level, legislatures have 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. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Arrangements with third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, or the FCA, which may constrain the business or financial arrangements and relationships through which companies research, sell, market and distribute pharmaceutical products. In addition, transparency laws and patient privacy laws can apply to the activities of pharmaceutical manufactures. The applicable federal, state and foreign healthcare laws and regulations that can affect a pharmaceutical company's operations include without limitation:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs, or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. 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 FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but such exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;

- The federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent 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, including providing inaccurate billing or coding information to customers or promoting a product off-label, 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 federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created federal criminal statutes that prohibit, among other things, 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, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates as well as their covered subcontractors. HITECH also created 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;
- The federal legislation commonly referred to as the Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics 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 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, covered manufacturers also are required to report information regarding their payments and other transfers of value to physician assistants, and nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- Analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local 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 laws that require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales representatives; and state 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.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations with respect to certain laws. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Prohibitions or restrictions on sales or withdrawal of future marketed products 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. Ensuring our business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects companies to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical company to incur significant legal expenses and divert management's attention from the operation of the business.

Regulations Governing Data Collection and the Use, Processing and Cross-Border Transfer of Personal Information

We also may be or may become subject to various state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

For example, California has enacted the California Consumer Privacy Act (CCPA), which created new individual privacy rights for California consumers (as defined in the law) and placed increased privacy and security obligations on entities handling personal data of consumers or households. Effective as of January 2020, the CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt out of certain sales or transfers of personal information, and also regulates employee information. On November 3, 2020, California passed the California Privacy Rights Act (CPRA) which builds on the CCPA and expands consumer privacy rights. The CPRA will go into effect on January 1, 2023 and will apply to information collected on or after January 1, 2022. While there is currently an exception in the CCPA and CPRA for protected health information that is subject to HIPAA, the CCPA and CPRA may impact our business activities. Virginia and Colorado have also passed comprehensive privacy laws that will become effective in 2013 and other U.S. states also are considering omnibus privacy legislation, and industry organizations regularly adopt and advocate for new standards in these areas.

In addition, as of May 25, 2018, the General Data Protection Regulation (GDPR) regulates the collection and use of personal data in the European Union (EU). The GDPR covers any business, regardless of its location, that provides goods or services to residents in the EU and, thus, could incorporate any activities we undertake in EU member states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information," which includes health and genetic information of individuals residing in the EU. The GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the EU to regions that have not been deemed to offer "adequate" privacy protections, such as the U.S. currently. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU member states, which may deviate slightly from the GDPR, may result in warning letters, mandatory audits and financial penalties, including fines of up to 4% of global revenues, or €20,000,000, whichever is greater.

Further to the United Kingdom's (UK) exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law (referred to as the 'UK GDPR'). The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU's GDPR, the European Commission ("EC") has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid innovation, intense and dynamic competition and a strong emphasis on proprietary products. While we believe that our technology, scientific knowledge and experience in the field of cellular immunotherapy provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions, as well as standard-of-care treatments, new products undergoing development and combinations of existing and new therapies. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies, including combinations thereof, that may become available in the future.

Cellular immunotherapies for the treatment of cancer have recently been an area of significant research and development by academic institutions and biopharmaceutical companies. Novartis AG (Novartis) and Kite Pharma, Inc. (Kite) were the first to obtain FDA approval for autologous CAR T-cell therapies for the treatment of certain cancers. Novartis obtained FDA approval to commercialize Kymriah in August 2017 for the treatment of children and young adults with relapsed / refractory B-cell acute lymphoblastic leukemia and, in May 2018, for the treatment of adults with relapsed / refractory diffuse large B-cell lymphoma. In October 2017, Kite obtained FDA approval to commercialize Yescarta for the treatment of adults with relapsed / refractory diffuse large B-cell lymphoma. More recently Bristol-Myers Squibb received FDA approval in 2021 for two new, autologous T-cell therapy products – Breyanzi for the treatment of relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, and Abecma for the treatment of adult patients with relapsed or refractory multiple myeloma.

We are developing our off-the-shelf NK- and T-cell product candidates for the treatment of cancer. While we believe our use of clonal master iPSC lines for the production of our off-the-shelf NK- and T-cell product candidates is highly differentiated, a number of clinical-stage companies are currently focused on the development of cellular immunotherapies for the treatment of cancer, including Adaptimmune Therapeutics plc, Allogene Therapeutics, Inc., Atara Biotherapeutics, Inc., Bristol-Myers Squibb Company, Caribou Biosciences, Inc., Cellectis SA, Celularity, Inc., CRISPR Therapeutics AG, Gilead Sciences, Inc., ImmunityBio, Inc., Intellia Therapeutics, Inc., Iovance Biotherapeutics, Inc., Johnson & Johnson, Legend Biotech Corporation, Nkarta, Inc., Novartis AG, Precision Biosciences, Inc., Sanofi SA, and Takeda Pharmaceutical Company Limited, and 2seventy bio, Inc. Preclinical-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We compete against our competitors in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and subject enrollment for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Many of our competitors, either alone or with their collaboration partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance.

We anticipate that we will face intense and increasing competition as new products enter the market and advanced technologies become available. We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third-party payers. Our commercial opportunity 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 any 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 ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Insurance

We maintain product liability insurance for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for products in development. However, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. In addition, we may not be able to obtain commercially reasonable product liability insurance for any products approved for marketing.

Human Capital

Our success as a company depends upon the innovation, drive, and dedication of our employees, and we seek to attract, incentivize, and reward creative and performance-driven employees. We believe our commitment to our human capital resources is an important component of our business that enables us to deliver superior performance in our industry.

We focus on identifying, recruiting, developing and retaining a team of highly talented and motivated employees. As of December 31, 2021, we employed 449 employees, all of whom are full-time employees, including 174 in research and development, 190 in clinical development, manufacturing and regulatory affairs and 85 in general and administrative. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective bargaining arrangements. We believe that our relationship with our employees is good, and we provide all employees with the opportunity to share their opinions in open dialogues with our human resources department and senior management.

Equity, Diversity, and Inclusion

We believe that an equitable, diverse, and inclusive workforce is a necessary foundation for innovation and dedication of our employees. Accordingly, we strive to promote diversity, inclusion and equal opportunity across the organization. We are committed to actively seeking out highly qualified women and minority candidates, as well as candidates with diverse backgrounds, skills and experiences. As of December 31, 2021, women made up 49% of our workforce and represented 47% of leadership positions at the Director level and above.

Health and Safety

The success of our business is fundamentally connected to the well-being, health and safety of our employees, and we are committed to providing a safe, healthy and secure workplace for our employees. We have an environmental health and safety program and maintain various compliance programs to support this commitment. We routinely train and educate our employees on workplace safety and security. Early in the pandemic we formed a COVID-19 task force dedicated to monitoring ongoing developments and guidance issued by local, state and public health authorities. Our COVID-19 task force provides regular updates and recommendations to our executive team, and provides timely communication and training to our employee base about the various safety measures we have put into place to protect their health and wellbeing. We took proactive action early on, implementing site enhancements and risk protocols, instituting remote working arrangements and adjusting our sick leave policies, and in our effort to support the safe occupancy of our sites, reconfigured work and common spaces to allow for social distancing increased office cleaning protocols, instituted daily health screenings and COVID-19 testing. As testing has become more readily available, we have offered both onsite testing and memberships to local medical clinics that offer testing. We continue to monitor and adjust our safety training and protocols as the pandemic continues to evolve.

Compensation and Benefits

We offer competitive pay, with performance-based bonuses and equity awards. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. We have a comprehensive benefits program offering flexibility for our employees' individual needs and requirements. Our benefits program includes a choice of medical plans, vision and dental coverage, flexible spending accounts for health and dependent day care needs, and income protection through life, AD&D, short term and long term disability coverage, sick leave, paid family leave, and generous paid time off. We offer a 401(k) retirement plan with company matching, an employee assistance program, and onsite fitness centers at no cost to our employees.

Employee Development and Engagement

We are focused on attracting and retaining a team of highly talented and motivated employees. We invest in and develop all levels of employees by engaging in ongoing career pathing and professional development conversations throughout an employee's tenure. In addition, we provide targeted leadership development programs for frontline leaders through executive leadership programs and offer a number of professional, management and leadership development training programs to help our employees develop cross-functional skills and tools to grow their careers.

Employees are incentivized for key contributions through awards programs that recognize their commitment and dedication by demonstrating our *Fate Pathways to Success*.

We focus on identifying, recruiting, developing and retaining a team of highly talented and motivated employees. We believe that our relationship with our employees is good. We believe our commitment to our human capital resources is an important component of our business that enables us to deliver superior performance in our industry. We provide all employees with the opportunity to share their opinions in open dialogues with our human resources department and senior management. We provide all

employees a wide range of professional development experiences, both formal and informal. The safety and wellbeing of our employees is a paramount value for us. Further, the health and wellness of our employees are critical to our success. We provide our employees with access to a variety of flexible and convenient health and wellness programs. Such programs are designed to support employees' physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors. Additionally, we provide competitive compensation and benefits. In addition to salaries, these programs, can include annual bonuses, stock-based compensation awards, a 401(k) plan with employee matching opportunities, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and family care resources. Further, in an effort to protect the health and safety of our employees, we took proactive action from the earliest signs of the COVID-19 outbreak, which included implementing social distancing policies at our facilities, facilitating remote working arrangements and imposing employee travel restrictions.

Corporate Information

We were incorporated in Delaware in 2007, and are headquartered in San Diego, CA. Our principal executive office is located at 12278 Scripps Summit Drive, San Diego, California 92131, and our telephone number is (858) 875-1800. Our website address is www.fatetherapeutics.com. We do not incorporate the information on or accessible through our website into this Annual Report on Form 10-K, and you should not consider any information on, or that can be accessed through, our website a part of this Annual Report on Form 10-K.

We own various U.S. federal trademark registrations and applications, and unregistered trademarks, including Fate Therapeutics®, our corporate logo. All other trademarks or trade names referred to in this document are the property of their respective owners. Solely for convenience, the trademarks and trade names in this document are referred to without the symbols® and ™, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

Available Information

We post our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, on the Investors section of our public website (www.fatetherapeutics.com) as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. In addition, you can read our SEC filings over the Internet at the SEC's website at www.sec.gov. The contents of these websites are not incorporated into this Annual Report on Form 10-K. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors

You should carefully consider the following risk factors, as well as the other information in this Annual Report on Form 10-K, and in our other public filings. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.

Risks Related to the Discovery, Development and Regulation of Our Product Candidates

If we fail to complete the preclinical or clinical development of, or to obtain regulatory approval for, our product candidates, our business would be significantly harmed.

All of our product candidates are currently in research or early clinical development. We have not completed clinical development of or obtained regulatory approval for any of our product candidates. Only a small percentage of research and development programs ultimately result in commercially successful products, and we cannot assure you that any of our product candidates will demonstrate the safety, purity and potency, or efficacy profiles necessary to support further preclinical study, clinical development or regulatory approval.

We may delay or cancel our ongoing and planned clinical development activities or research and development activities for any of our product candidates for a variety of reasons, including:

- determining that a product candidate is ineffective, causes harmful side effects, or otherwise presents unacceptable safety risks during clinical trials or has an unfavorable toxicity profile in preclinical studies to support clinical investigation;

- difficulties in manufacturing or distributing a product candidate, including the inability to manufacture and distribute a product candidate in a sufficient quantity, suitable form, or in a cost-effective manner, or under protocols and processes and with materials and facilities acceptable to the FDA for the conduct of clinical trials or for marketing approval;
- our prioritization of other of our product candidates for advancement or the emergence of competing product candidates developed by others, including a decision to cease research and development of any existing product candidate due to the potential obsolescence of our product candidate by a competing product or product candidate or our determination that another of our existing or future product candidates has greater potential for clinical development, regulatory approval, or commercialization, including potentially greater therapeutic benefit, a more favorable safety or efficacy profile, a more consistent or more cost effective manufacturing process, or more a favorable commercial profile, including greater market acceptance or commercial potential, or more advantageous intellectual property position;
- challenges and delays in trial execution associated with our testing of multiple product candidates in the same indication in different clinical trials, as well as competition from biotechnology and pharmaceutical companies, universities, and other research institutions for patients and clinical trial sites;
- the proprietary rights of third parties, which may preclude us from developing, manufacturing or commercializing a product candidate;
- determining that a product candidate may be uneconomical to develop, manufacture, or commercialize, or may fail to achieve market acceptance or an adequate pricing and reimbursement profile;
- our inability to secure or maintain relationships with strategic partners that may be necessary for advancement of a product candidate into or through clinical development, regulatory approval and commercialization in any particular indication(s) or geographic territory(ies); or
- difficulty establishing predictive preclinical models for demonstration of safety and efficacy of a product candidate in one or more potential therapeutic areas for clinical development.

Additionally, we will only be able to obtain regulatory approval to market a product candidate if we can demonstrate, to the satisfaction of the FDA or comparable foreign regulatory authorities, in well-designed and conducted clinical trials that such product candidate is manufactured in accordance with applicable regulatory requirements, is safe, pure and potent, or effective, and otherwise meets the appropriate standards required for approval for a particular indication. Our ability to obtain regulatory approval of our product candidates depends on, among other things, completion of additional preclinical studies, process development and manufacturing activities, and clinical trials, whether our clinical trials demonstrate statistically significant efficacy with safety profiles that do not potentially outweigh the therapeutic benefit, and whether regulatory agencies agree that the data from our clinical trials and our manufacturing operations are sufficient to support approval. In addition, the approval by the FDA of new products in the same indications that we are studying may change the standard of care, and this may result in the FDA or other regulatory agencies requesting that we conduct additional studies to show that our product candidate is superior to the new standard of care. Securing regulatory approval also requires the submission of information about product manufacturing operations to, and inspection of manufacturing facilities by, the relevant regulatory authority. The final results of our current and future clinical trials may not meet the FDA's or other regulatory agencies' requirements to approve a product candidate for marketing, and the regulatory agencies may otherwise determine that our manufacturing operations are insufficient to support approval. We may need to conduct preclinical studies and clinical trials that we currently do not anticipate, including as a result of changes in the standard of care. If we fail to complete preclinical or clinical development of, or obtain regulatory approval for, our product candidates, we will not be able to generate any revenues from product sales and our ability to receive milestone or other payments under any collaboration agreements may be impaired, which will harm our business, prospects, financial condition and results of operations.

We may face delays in initiating, conducting or completing our clinical trials, and we may not be able to initiate, conduct or complete them at all.

We are heavily dependent on our ability to complete the clinical development of, and obtain regulatory approval for, our product candidates. We have not completed the clinical trials necessary to support an application for approval to market any of our product candidates. We, or any investigators who initiate or conduct clinical trials of our product candidates, may experience delays in our current or future clinical trials, and we do not know whether we or our investigators will be able to initiate, enroll patients in, or complete, clinical trials of our product candidates on time, if at all. Current and future clinical trials of our product candidates may be delayed, unsuccessful or terminated, or not initiated at all, as a result of many factors, including factors related to:

- difficulties in identifying eligible patients for participation in clinical trials of our product candidates, due in part to our focus on the development of certain of our product candidates for the treatment of rare diseases;

- difficulties enrolling a sufficient number of suitable patients to conduct clinical trials of our product candidates, including difficulties resulting from patients enrolling in studies of therapeutic product candidates sponsored by us or our competitors and difficulties resulting from patient availability as a result of shelter-in-place orders, mandated travel restrictions, prioritization of hospital and other medical resources toward pandemic efforts, policies and procedures implemented at clinical sites with respect to the conduct of clinical trials, and other precautionary measures taken in treating patients or in practicing medicine in response to the ongoing COVID-19 pandemic;
- difficulties determining suitable doses and schedules of our novel cell product candidates for evaluation in clinical trials;
- difficulties in obtaining agreement from regulatory authorities on study endpoints and/or study duration, achieving study endpoints, the amount and sufficiency of data demonstrating efficacy and safety, and completing data analysis in clinical trials for any of our product candidates;
- difficulties in obtaining agreement from regulatory authorities on the preclinical safety and efficacy data, the manufacturing requirements, and the clinical trial design and parameters necessary for an IND application to go into effect to initiate and conduct clinical trials for any of our current product candidates and any other product candidates that we may identify;
- the occurrence of unexpected safety issues or adverse events in any ongoing or future clinical trials of our product candidates, including in trials of our product candidates conducted by investigator-sponsors;
- securing and maintaining the support of clinical investigators and investigational sites, including investigators and sites who may conduct clinical trials under an investigator-sponsored IND with our financial support, and obtaining institutional review board (IRB) approval at each site for the conduct of our clinical trials;
- governmental or regulatory delays, including any delays due to limitations on the availability of governmental and regulatory agency personnel to review regulatory filings, conduct site inspections or engage in discussions with us as a result of the COVID-19 pandemic, failure to obtain regulatory approval, or uncertainty or changes in U.S. or foreign regulatory requirements, policy or guidelines;
- limitations on clinical trial conduct at our clinical trial sites resulting from prioritization of hospital and other medical resources toward COVID-19 pandemic efforts, policies and procedures implemented at clinical sites with respect to the conduct of clinical trials including those relating to site initiation, study monitoring, and data collection and analysis, and other precautionary measures taken in treating patients or in practicing medicine in response to the COVID-19 pandemic;
- reaching agreement on acceptable terms with third-party service providers and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different service providers and clinical trial sites;
- failure, by us or third parties that we contract with, to manufacture certain of our product candidates consistently, and in sufficient quantities, in accordance with our protocol-specified manufacturing requirements and applicable regulatory requirements;
- our failure, or the failure of investigators, third-party service providers, or clinical trial sites, to ensure the proper and timely conduct of and analysis of data from clinical trials of our product candidates;
- inability to reach agreement on clinical trial design and parameters with regulatory authorities, investigators, and IRBs;
- failure or delays in obtaining sufficient quantities of suitable raw materials, components, and equipment necessary for the manufacture of any product candidate, including any inability to obtain materials as a result of supply chain issues related to the COVID-19 pandemic;
- challenges in distributing our product candidates to clinical trial sites, or failure to establish effective protocols for the supply and transport of our product candidates;
- the costs of conducting clinical trials or manufacturing of our product candidates being greater than we anticipate or the timelines for these activities being longer than we anticipate;
- regulatory authorities or data monitoring committees requiring or recommending suspension, termination or a clinical hold for various reasons, including concerns about patient safety or the safety of novel therapeutics derived from pluripotent or genome edited therapies;
- the serious, life-threatening diseases of the patients enrolled in our clinical trials, who may die or suffer adverse medical events during the course of the trials for reasons that may not be related to our product candidates;

- failure of patients to complete clinical trials or adhere to study protocols due to safety issues, side effects, disruptions in study conduct, including study monitoring, data collection and analysis, restrictions on hospital visits or travel relating to the COVID-19 pandemic, or other reasons; and
- approval of competitive agents that may materially alter the standard of care on which a clinical development plan was based, which may require new or additional trials, or render our product candidates or clinical trial designs obsolete.

If there are delays in initiating or conducting any clinical trials of our product candidates or any of these clinical trials are terminated before completion, the commercial prospects of our product candidates will be harmed. In addition, any delays in initiating, conducting or completing our clinical trials or adjustments to certain of our study protocols and procedures, including as a result of the COVID-19 pandemic, will increase our costs, slow down our product candidate development and regulatory approval process, and jeopardize our ability to gain regulatory approval, commence product sales and generate revenues. Furthermore, many of the factors that cause, or lead to, a delay in the initiation, conduct or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any of these occurrences would significantly harm our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

The manufacture and distribution of our cell product candidates, particularly our iPSC-derived cell product candidates, is complex and subject to a multitude of risks. These risks could substantially increase our costs and limit the clinical and commercial supply of our product candidates, and the development and commercialization of our product candidates could be substantially delayed or restricted if the FDA or other regulatory authorities impose additional requirements on our manufacturing operations or if we are required to change our manufacturing operations to comply with regulatory requirements.

The manufacture and supply of our cell product candidates involve novel processes that are more complex than those required for most small molecule drugs and other cellular immunotherapies, and accordingly present significant challenges and are subject to multiple risks. For our iPSC-derived product candidates, these complex processes include reprogramming human fibroblasts to obtain iPSCs, in some cases genetically engineering these iPSCs, and differentiating the iPSCs to obtain the desired cell product candidate. As a result of the complexities in manufacturing biologics and distributing cell therapies, the cost to manufacture and distribute biologics and cell therapies in general, and our cell product candidates in particular, is generally higher than traditional small molecule chemical compounds. In addition, 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.

We have limited experience in the manufacture of cell-based therapies. We are still developing optimized and reproducible manufacturing processes for clinical and commercial-scale manufacturing of our product candidates, and none of our manufacturing processes have been validated for commercial production of our product candidates. We may face several challenges as we scale our manufacturing for large-scale clinical trials or commercial-scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. In addition, we are still optimizing our protocols for the supply and transport of our product candidates for distribution to clinical trial sites. Although we are working to develop reproducible and commercially viable manufacturing processes for our product candidates, and effective protocols for the supply and transport of our product candidates, doing so is a difficult and uncertain task.

We may make changes or be required by the FDA to make changes to our manufacturing processes, including materials used in manufacturing our product candidates, as we continue to develop and refine the manufacturing and distribution processes for our product candidates for advanced clinical trials and commercialization, and we cannot be sure that even minor changes in these processes will not cause our product candidates to perform differently and affect the results of our ongoing and planned clinical trials or the performance of the product once commercialized. In some circumstances, changes in our manufacturing operations, including to our protocols, processes, materials or facilities used, may require us to perform additional preclinical or comparability studies, or to collect additional clinical data from patients prior to undertaking additional clinical studies or filing for regulatory approval for a product candidate. These requirements may lead to delays in our clinical development and commercialization plans for our product candidates, and may increase our development costs substantially.

The manufacturing processes for any products that we may develop are subject to FDA and foreign regulatory authority approval requirements, and we will need to meet, and our contract manufacturing organizations (CMOs) or other third party manufacturers will need to meet, all applicable FDA and foreign regulatory authority requirements on an ongoing basis. Our existing product candidates are currently manufactured by us or by third-party cell processing facilities or CMOs, including facilities operated by or affiliated with our clinical sites, and our current manufacturing operations, including protocols, processes, materials, and facilities, may not support regulatory approval of our existing product candidates. We may be required to identify alternative protocols, processes, materials or facilities for the manufacture of any of these product candidates in compliance with applicable regulatory requirements. In addition, we may be required to make changes to our protocols for the supply and transport of our product candidates to enable effective distribution of our product candidates. Any modifications to our manufacturing and supply protocols,

processes, materials or facilities, and any delays in, or inability to, establish acceptable manufacturing and supply operations for our product candidates could require us to incur additional development costs or result in delays to our clinical development. If we or our CMOs or other third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the regulatory approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs or other third-party manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Additionally, changes in regulatory requirements may require us or our third-party manufacturers to perform additional studies or to modify protocols, processes, materials or facilities for the manufacture of our product candidates or any components thereof. Any of these challenges could delay initiation or completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and prospects.

A disruption to our manufacturing operations, or our or our third-party suppliers' or manufacturers' inability to manufacture sufficient quantities of our product candidates at acceptable quality levels or costs, or at all, would materially and adversely affect our business.

Developing manufacturing processes to support clinical studies and commercialization requirements is a difficult and uncertain task, and there are risks associated with scaling to the level required for clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability and purity issues, lot consistency, and timely availability of acceptable reagents and raw materials. If we are unable to scale to the level required for the conduct of clinical trials or commercialization, we may not be able to produce our product candidates in a sufficient quantity to conduct our ongoing and planned clinical trials, or to meet demand if any product candidates are approved for commercialization. We have not yet caused any of our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates.

We are substantially dependent on our own internal manufacturing facilities in San Diego, California for the production of our product candidates, and we rely, and expect to continue to rely, on third parties for the manufacture of certain components and also to manufacture our product candidates for use in conducting clinical trials. The facilities used to manufacture our product candidates, including our own facilities, must be evaluated by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit an application to the FDA or other foreign regulatory agencies. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it later finds deficiencies or withdraws any such approval in the future, we may not be able to locate additional or replacement facilities to produce such product candidates or materials in a timely manner and on commercially reasonable terms, or at all. This would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Because we rely on our own manufacturing facility to produce our product candidates and on third parties for the manufacture of certain components and the product candidates themselves, we are required to transfer certain manufacturing process know-how and certain intermediates to third parties, including larger-scale facilities operated by a CMO or by us, to facilitate manufacture of our product candidates for clinical trials and commercialization. Transferring manufacturing testing and processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We and any CMOs or third parties that we engage for manufacturing our product candidates will need to conduct significant development work to transfer these processes and manufacture each of our product candidates for clinical trials and commercialization. In addition, we may be required to demonstrate the comparability of material generated by any CMO or third parties that we engage for manufacturing our product candidates with material previously produced and used in testing. Any inability to manufacture comparable drug product by us or our CMOs could delay the continued development of our product candidates.

In addition to relying on third parties for the manufacture of our product candidates, we also manufacture certain of our product candidates ourselves, and intend to manufacture some or all of the clinical supply of our iPSC-derived NK-cell and T-cell product candidates for our ongoing and planned clinical trials. To do so, we will need to scale up our own manufacturing operations, as we do not currently have the infrastructure or capability internally to manufacture sufficient quantities of each of our product candidates to support the conduct of each of our clinical trials or commercialization of each of our product candidates, if approved. Accordingly, we will be required to make significant investments to expand our existing GMP manufacturing capabilities and facilities, establish additional GMP manufacturing facilities, conduct GMP production, and process and scale up development and technology transfer activities for the manufacture of our product candidates, and our efforts to scale our own manufacturing operations may not succeed.

Even if we are successful in developing manufacturing capabilities sufficient for clinical and commercial supply, problems with our manufacturing operations or those of the third-party manufacturers upon which we rely, including difficulties with production

costs and yields, quality control, stability of the product, quality assurance testing, operator error, shortages of qualified personnel, facility shutdowns due to the ongoing COVID-19 pandemic, natural disasters or other reasons, as well as compliance with strictly enforced federal, state and foreign regulations, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient supplies of our product candidates for our ongoing and planned clinical trials or eventual commercialization. For example, in response to governmental shelter-in-place orders resulting from the COVID-19 pandemic, we or our third-party manufacturers have been, and may from time to time be required to limit our or their on-site staff's availability to conduct manufacturing activities at our or their respective facilities, and we and our third-party manufacturers may encounter problems with shortages of qualified personnel and key contractors, and delays or pauses in the production and delivery of laboratory equipment, materials and supplies necessary for the manufacture of our product candidates. These problems may include workforce reductions, employee absenteeism and attrition, and supply chain failures or delays relating to the COVID-19 pandemic or other events affecting raw material supply or manufacturing capabilities. Several vaccines for COVID-19 have been granted Emergency Use Authorization by the FDA, and two of those later received marketing approval. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the product candidates needed for our clinical trials, which could lead to delays in these trials. Further, delays in regulatory inspections, commissioning and receiving regulatory approvals for our manufacturing capabilities or facilities, including new facilities, as a result of limited governmental resources due to the COVID-19 pandemic or otherwise, could delay our development plans, including the initiation and conduct of our ongoing and planned clinical trials. In addition, we and our third-party manufacturers may have limited manufacturing capacity for certain product candidates or components, and we may fail to locate suitable additional or replacement manufacturing capacity, including for the manufacture of our product candidates in compliance with cGMP or cGTP, on a reasonable basis or at all. Any such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction or imposing civil and criminal penalties.

Furthermore, certain of the components currently used in manufacturing our product candidates are research-grade only, and we may encounter problems obtaining or achieving adequate quantities and quality of clinical grade materials that meet FDA, European Medicines Agency, or other applicable standards or specifications with consistent and acceptable production yields and costs. In addition, if contaminants are discovered in our supply of product candidates or in our manufacturing facilities or those of our third-party suppliers and manufacturers, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any such events could delay or prevent our ability to obtain regulatory approval for or commercialize our product candidates, which would adversely affect our business, prospects, financial condition and results of operations.

We are subject to risks associated with the ongoing spread of the coronavirus, SARS-CoV-2 (COVID-19), and the global pandemic could seriously impact the research and development of our product candidates.

The ongoing COVID-19 pandemic has broadly affected the global economy, resulted in significant travel and work restrictions in many regions and put a significant strain on healthcare resources. The pandemic has had, and we expect it will continue to have, an impact on our operations and on the operations of our collaborators, third-party contractors and other entities, including governmental agencies with which we interact. In particular, state and local regulations requiring during certain periods that a significant portion of our employees work remotely has had an impact on our operations and research and development of our product candidates. We have also experienced delays in obtaining materials and supplies needed to maintain our operations and manufacture our product candidates as a result of production shortages experienced by our suppliers. Additionally, at times we have been subject to temporary pauses in enrollment and dosing implemented by some clinical trial sites due to COVID-19, and some clinical trial sites have also restricted initiation of new trials at times as well as visits by sponsors and clinical research organizations (CROs) for ongoing trials to protect both site staff and patients from possible COVID-19 exposure.

The COVID-19 pandemic, including the emergence of new variants, has impacted, and may in the future impact, the clinical development of our product candidates if we are subject to restrictions or limitations on, or delays in, the performance of study procedures (particularly any procedures that may be deemed non-essential), participant dosing, distribution of our product candidates or clinical trial materials, study monitoring, or site inspections and data analysis, including as a result of changes in hospital or research institution policies, federal, state or local regulations, prioritization of hospital and other medical resources toward pandemic efforts, reduced availability of site staff supporting the conduct of clinical trials, heightened risks of exposure of study participants, principal investigators or site staff to COVID-19 if an outbreak occurs in their geographic region, or other reasons related to the pandemic. Quarantine or other travel limitations (whether voluntary or required) also may impede participant movement, affect access to study sites, or interrupt healthcare services.

Furthermore, the pandemic could cause delays in review and response times by the FDA and other regulatory agencies, or such health regulatory agencies may refuse to accept data from our clinical trials due to mitigation strategies we implement in response to the COVID-19 pandemic and current regulatory guidance. In addition, our ability to manufacture and ship our product candidates for

our clinical trials may be impacted if we, or any third parties which manufacture and supply materials used in either the manufacture of our product candidates or the conduct of our research and development activities, or which perform certain testing relating to our product candidates, are adversely impacted by restrictions resulting from the coronavirus outbreak. There is also the potential that manufacturing facilities, equipment, and materials required for manufacture or administration of our product candidates could be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, which may make it more difficult to obtain materials, equipment, or manufacturing slots necessary for the clinical supply of our product candidates.

The extent to which the pandemic affects our operations and the research and development of our product candidates will depend on continuously changing circumstances, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, including the emergence of new variants of the virus, such as the Delta and Omicron variants, which may impact rates of infection and vaccination efforts, developments or perceptions regarding the safety of vaccines, future waves of infection, and the effectiveness of actions taken to contain the pandemic or mitigate its impact, including vaccination campaigns. While the ultimate impact of the COVID-19 pandemic on our business is highly uncertain, any negative impacts that materialize could materially adversely affect our clinical development and operations, financial performance and stock price.

Because our approach to the development of product candidates is based on novel and unproven technologies, it is subject to a substantial degree of technological uncertainty and we may not succeed in developing any of our product candidates.

All of our current product candidates are based on our novel iPSC platform, and some of our product candidates utilize novel genome editing technologies. To date, no iPSC-derived therapeutic product candidates have been approved in the United States or worldwide, and there have been only a limited number of regulatory approvals of genome edited therapeutics, and similarly a limited number of clinical trials involving the use of a therapeutic product candidate manufactured using a master iPSC line or genome edited cells. The development of such complex cell therapies is a relatively new and emerging field, and the scientific research that forms the basis of our efforts to discover and develop iPSC-derived and genome edited cellular immunotherapies is ongoing. We may determine to incorporate information learned from this research into the design of our ongoing Phase 1 clinical trials of our iPSC product candidates, as well as our planned future clinical trials, which could delay or impair our clinical development activities. We may ultimately discover that our product candidates do not possess certain properties required for therapeutic effectiveness or protection from toxicity in our target patient populations, or they may exhibit undesirable side effects as more patient data become available. In addition, our product candidates may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. It may take many years before we develop a full understanding of the pharmacological properties of our product candidates, and we may never know precisely how they function *in vivo*. Moreover, our genome editing approach may cause unintended changes to the DNA such as a non-target site gene editing, a large deletion or a DNA translocation, any of which could lead to oncogenesis or other adverse effects. As with any new biologic or product developed using novel technologies, our product candidates have an unknown immunogenicity profile. As a result, our cellular immunotherapy product candidates may trigger immune responses that inhibit their therapeutic effects or cause adverse side effects. In addition, one or more of our product candidates may:

- be found ineffective or cause harmful side effects during preclinical studies or clinical trials;
- fail to receive necessary regulatory approvals on a timely basis or at all;
- be precluded from commercialization by proprietary rights of third parties;
- be difficult to manufacture on a large scale; or
- be uneconomical to commercialize or fail to achieve market acceptance.

Any such problems that affect one of our product candidates may have an unfavorable impact on all of our product candidates. As a result, we may never succeed in developing a marketable product and we may never become profitable, which would have an adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

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

We are required to identify and enroll a sufficient number of patients with the disease under investigation for each of our ongoing and planned clinical trials of our product candidates, and we may not be able to identify and enroll a sufficient number of patients, or those with required or desired characteristics and who meet certain criteria, in a timely manner. In addition, we will be competing with other clinical trials of product candidates being developed by our competitors in the same therapeutic areas, and potential patients who might be eligible for enrollment in one of our clinical trials may instead choose to enroll in a trial being conducted by one of our competitors.

Our ability, and the ability of investigators, to enroll patients in our ongoing and planned clinical trials of our product candidates is affected by factors including:

- the ability to identify, solicit and recruit a sufficient number of patients;
- severity of the disease under investigation;
- design of the trial protocol;
- the relatively small size and nature of the patient populations for certain of our clinical trials;
- eligibility criteria for the trials in question;
- perceived risks and benefits of the product candidate under study, including any perceived risks associated with iPSC-derived product candidates, which we believe are the first ever iPSC-derived cell therapies cleared by the FDA for clinical investigation in the United States;
- the availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- the availability of time and resources at the limited number of institutions at which our clinical trials are or will be conducted, including any constraints on resources, or policies and procedures implemented, at hospitals and clinical trial sites as a result of the COVID-19 pandemic;
- the availability of cells suitable for the manufacture of our clinical product candidates from eligible and qualified donors for certain of our product candidates;
- the ability to monitor patients adequately during and after treatment, including through remote monitoring if required as a result of precautionary changes implemented at certain clinical trial sites as a result of the COVID-19 pandemic; and
- the proximity and availability of clinical trial sites for prospective patients.

In addition, certain of our clinical trial sites at times have delayed or paused patient enrollment in clinical trials as a result of the COVID-19 pandemic, and quarantines or other travel limitations relating to the COVID-19 pandemic may impede patient movement and affect access to study sites, which may further impact patient enrollment in our clinical trials. The extent and duration of such delays and disruptions, and the overall impact on the timing and conduct of our clinical trials, are uncertain. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

The clinical development of our product candidates could be substantially delayed if we are required to conduct unanticipated studies, including preclinical studies or clinical trials, or if the FDA imposes other requirements or restrictions including on the manufacture, of our product candidates.

The FDA may require us to generate additional preclinical, product, manufacturing, or clinical data as a condition to continuing our current clinical trials, or initiating and conducting any future clinical trials of our current product candidates or other cell product candidates that we may identify. Additionally, the FDA may in the future have comments, or impose requirements, on the conduct of our clinical trials or the initiation of clinical trials or any of our other iPSC-derived cell product candidates, including the protocols, processes, materials and facilities we use to manufacture our product candidates and potential future product candidates in support of clinical trials. Any requirements to generate additional data, or redesign or modify our protocols, processes, materials or facilities, or other additional comments, requirements or impositions by the FDA, may cause delays in the initiation or conduct of the current or future clinical trials for our product candidates and subsequent development activities for our product candidates, and could require us to incur additional development or manufacturing costs and resources, seek funding for these increased costs or resources or delay our timeline for, or cease, our preclinical or clinical development activities for our product candidates, or could create uncertainty and additional complexity in our ability to obtain regulatory approval for our product candidates.

Further, if the results of our clinical trials are inconclusive, or if there are safety concerns or adverse events associated with our existing product candidates or any other product candidates we may identify, we may:

- be delayed in obtaining, or unable to obtain, regulatory approval for such product candidates;
- be required to amend the protocols for our clinical trials, perform additional nonclinical studies or clinical trials to support approval or be subject to additional post-marketing testing requirements;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings or contraindications; or
- in the event a product candidate is approved, have regulatory authorities withdraw their approval of the product or impose restrictions on its use.

Even if our current and planned clinical trials are successful, we will need to conduct additional clinical trials, which may include registrational trials, trials in additional patient populations or under different treatment conditions, and trials using different manufacturing protocols, processes, materials or facilities or under different manufacturing conditions, before we are able to seek approvals for our product candidates from the FDA and regulatory authorities outside the United States to market and sell these product candidates. If we fail to meet the requirements to support continued clinical development, our clinical development activities for any of our product candidates are delayed or suspended, or we fail to obtain or maintain regulatory approvals with an acceptable scope, our business, prospects, financial condition and results of operations will be harmed.

We are pursuing multiple programs and product candidates in our novel cell therapy development pipeline using an approach that is designed to enable rapid incorporation of new product features. If we elect to incorporate these new features into next-generation product candidates, this may render our existing product candidates obsolete, and we may devote our limited resources in pursuit of a particular program for which there is a greater potential for success and fail to capitalize on development opportunities or product candidates including those which may be more advanced in development.

We focus on the development of programmed cellular immunotherapies for patients with cancer, including off-the-shelf NK- and T-cell product candidates derived from clonal master engineered iPSC lines. Because our iPSC product platform is designed to enable rapid incorporation of novel functional product features in an evolving clinical setting, we may elect to incorporate these discoveries into next-generation product candidates that render our existing product candidates, including product candidates under clinical development, obsolete. Additionally, because we have limited financial and personnel resources, we may elect or be required to abandon or delay the pursuit of opportunities with existing or future product candidates, including those that may be more advanced in development than those we ultimately elect to pursue. Due to these factors, our spending on current and future research and development programs and product candidates and the scientific innovation arising from these expenditures, may not yield commercially viable product candidates.

We study our product candidates in patient populations with significant comorbidities that may result in deaths or serious adverse events or unacceptable side effects and require us to abandon or limit our clinical development activities.

Patients treated with our current product candidates may also receive chemotherapy, radiation, and/or other high dose or myeloablative treatments in the course of treatment of their disease, and may therefore experience side effects or adverse events, including death, that are unrelated to our product candidates. While these side effects or adverse events may be unrelated to our product candidates, they may still affect the success of our clinical studies. The inclusion of critically ill patients in our clinical studies may result in deaths or other adverse medical events due to underlying disease or to other therapies or medications that such patients may receive. Any of these events could prevent us from advancing our product candidates through clinical development, and from obtaining regulatory approval, and would impair our ability to commercialize our product candidates. Any inability to advance our existing product candidates or any other product candidate through clinical development would have a material adverse effect on our business, and the value of our common stock would decline.

Because our product candidates are based on novel technologies, it is difficult to predict the regulatory approval process and the time, the cost and our ability to successfully initiate, conduct and complete clinical development, and obtain the necessary regulatory and reimbursement approvals, required for commercialization of our product candidates.

Our cell programming technology and platform for generating cell therapy products using iPSCs represent novel therapeutic approaches, and to our knowledge there are currently no iPSC-derived cell products approved anywhere in the world for commercial sale. As such, it is difficult to accurately predict the type and scope of challenges we may incur during development of our product candidates, and we face uncertainties associated with the preclinical and clinical development, manufacture and regulatory requirements for the initiation and conduct of clinical trials, regulatory approval, and reimbursement required for successful commercialization of these product candidates. In addition, because our iPSC-derived cell product candidates are all in the early clinical or preclinical stage, we are currently assessing safety in humans and have not yet been able to assess the long-term effects of treatment. Animal models and assays may not accurately predict the safety and efficacy of our product candidates in our target patient populations, and appropriate models and assays may not exist for demonstrating the safety and purity of our product candidates, as required by the FDA and other regulatory authorities for ongoing clinical development and regulatory approval.

The preclinical and clinical development, manufacture, and regulatory requirements for approval of novel product candidates such as ours can be more expensive and take longer than for other more well-known or extensively studied pharmaceutical or

biopharmaceutical product candidates due to a lack of prior experiences on the side of both developers and regulatory agencies. Additionally, due to the uncertainties associated with the preclinical and clinical development, manufacture, and regulatory requirements for approval of our product candidates, we may be required to modify or change our preclinical and clinical development plans or our manufacturing activities and plans, or be required to meet stricter regulatory requirements for approval. Any such modifications or changes could delay or prevent our ability to develop, manufacture, obtain regulatory approval or commercialize our product candidates, which would adversely affect our business, financial condition and results of operations.

Cellular immunotherapies, and iPSC-derived cell therapies in particular, represent relatively new therapeutic areas, and the FDA has cautioned consumers about potential safety risks associated with cell therapies. To date, there are relatively few approved cell therapies, and in October 2021, it was reported that the FDA placed a clinical hold on all allogeneic CAR T-cell clinical studies being conducted by a company that reported a chromosomal abnormality in a patient treated with one of their product candidates highlighting the technical and regulatory risk of working with new technology. As a result, the regulatory approval process for product candidates such as ours is uncertain and may be more expensive and take longer than the approval process for cell therapy product candidates based on other, better known or more extensively studied technologies and therapeutic approaches.

Regulatory requirements in the United States and in other countries governing cell therapy products have changed frequently and the FDA or other regulatory bodies may change the requirements, or identify different regulatory pathways, for approval for any of our product candidates. For example, within the FDA, the Center for Biologics Evaluation and Research, or CBER, restructured and created a new Office of Tissues and Advanced Therapies to better align its oversight activities with FDA Centers for Drugs and Medical Devices. It is possible that over time new or different divisions may be established or be granted the responsibility for regulating cell and/or gene therapy products, including iPSC-derived cell products, such as ours. As a result, we may be required to change our regulatory strategy or to modify our applications for regulatory approval, which could delay and impair our ability to complete the preclinical and clinical development and manufacture of, and obtain regulatory approval for, our product candidates. Changes in regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with the FDA and other regulatory authorities, and our product candidates will likely be reviewed by an FDA advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product revenues to maintain our business.

Preliminary data and interim results we disclose may change as more patient data becomes available or as we make changes to our protocols or manufacturing processes, and such interim results and results from earlier studies may not be predictive of the final results, or of later studies or future clinical trials.

We may from time to time disclose results from preclinical testing or preliminary data or interim results from clinical studies of our product candidates. Such results from preclinical testing, process development and manufacturing activities, and clinical studies, including interim clinical trial results as of specified data cutoff dates and results of earlier clinical studies with similar product candidates, are not necessarily predictive of future results, including later clinical trial results.

The results of our current and future clinical trials may differ from results achieved in earlier preclinical and clinical studies for a variety of reasons, including:

- we may not demonstrate the potency and efficacy benefits observed in previous studies;
- our efforts to improve, standardize and automate the manufacture and supply of our product candidates and any resulting deviations in the manufacture of our product candidates, may adversely affect the safety, purity, potency, stability, or efficacy of such product candidates;
- differences in study design, including differences in conditioning regimens, eligibility criteria, and patient populations;
- advancements in the standard of care may affect our ability to demonstrate efficacy or achieve study endpoints in our current or future clinical trials; and
- safety issues or adverse events in patients who enroll in our current or future clinical trials.

Additionally, some clinical trials of our product candidates performed to date were generated from open-label studies and are being conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at

different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which treatment regimen patients have received and may interpret the information of the treated group more favorably given this knowledge. Accordingly, the preliminary data from our Phase 1 clinical trials of certain of our product candidates may not be predictive of future clinical trial results for these or other product candidates when studied in a controlled environment or larger patient populations.

From time to time, we also publish interim, "top-line," or preliminary data from our clinical studies based on a preliminary analysis of then-available data. Preliminary or interim data from clinical trials that we are conducting are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, the duration of treatment increases and more patient data become available. For example, although we reported positive interim clinical data from our FT516 and FT596 programs for patients with relapsed / refractory B-cell lymphoma, we may encounter dose-limiting toxicities or unacceptable side effects for these product candidates as dose escalation and expansion progresses in our clinical trials and additional patient data become available. Our preliminary or interim results and related conclusions also are subject to change following a more comprehensive review of the data related to the particular study or trial. 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. Material adverse changes between preliminary, "top-line," or interim data and final data could significantly harm our business prospects, financial condition and results of operations.

Results of clinical testing of any of our existing or future product candidates may fail to show the necessary safety and efficacy required for regulatory approval.

Before obtaining marketing approval from regulatory authorities for the sale of any of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy in humans of any such product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our product candidates have a limited history of being evaluated in human clinical trials. Any of our product candidates may fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through initial clinical trials.

There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit, or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

If our product candidates are ultimately not approved for any reason, our business, prospects, results of operations and financial condition would be adversely affected. In addition, the standard of care may change with the approval of new products for the same indications that we are studying.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

Any product candidate for which we obtain marketing approval, along with the manufacturing protocols, processes, materials and facilities, qualification testing, post-approval clinical data, labeling and promotional activities for such product, will be subject to continual and additional requirements of the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information, reports, registration and listing requirements, requirements relating to current cGMP, applicable product tracking and tracing requirements, quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of pharmaceutical and biological products to ensure such products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Later discovery of previously unknown problems with our product candidates, manufacturing operations, or failure to comply with regulatory requirements, may lead to various adverse conditions, including significant delays in bringing our product candidates to market and/or being precluded from manufacturing or selling our product candidates, any of which could significantly harm our business.

We have received regenerative medicine advanced therapy, or RMAT, designation for the treatment of relapsed/refractory diffuse large B-cell lymphoma, and we may in the future seek RMAT designation for some of our other product candidates, but such designation may not actually lead to a faster development or regulatory review or approval process and we may be unable to obtain or maintain the benefits associated with such designation.

We have received regenerative medicine advanced therapy, or RMAT, designation from the FDA for FT516 for the treatment of relapsed/refractory diffuse large B-cell lymphoma. A product candidate is eligible for RMAT designation if: (1) it is a cell therapy, therapeutic tissue engineering product, human cell or tissue product, or a combination product using any such therapies or products; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) there is preliminary clinical evidence that indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. This program is intended to facilitate efficient development and expedite review of RMATs. A BLA for a product candidate with RMAT designation may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with the FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A product candidate that has RMAT designation and is subsequently granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. RMAT designation is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for RMAT designation, the FDA may disagree and instead determine not to grant such designation. In any event, the receipt of RMAT designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for RMAT designation, the FDA may later decide that the product candidate no longer meet the conditions for qualification.

We may rely on orphan drug status to develop and commercialize certain of our product candidates, but orphan drug designations may not confer marketing exclusivity or other expected commercial benefits and we may not be able to obtain orphan drug designations for our other product candidates.

We may rely on orphan drug exclusivity for product candidates that we may develop. Orphan drug status confers seven years of marketing exclusivity in the United States under the Federal Food, Drug, and Cosmetic Act, and up to ten years of marketing exclusivity in Europe for a particular product in a specified indication, subject to certain conditions. However, we may be unable to obtain orphan drug designations for any of our product candidates that we are currently developing or may pursue. Even if we do obtain orphan drug designations and are the first to obtain marketing approval of our product candidates for the applicable indications, we will not be able to rely on these designations to exclude other companies from manufacturing or selling biological products using the same principal molecular structural features for the same indication beyond these timeframes. Furthermore, any marketing exclusivity in Europe can be reduced from ten years to six years if the initial designation criteria have significantly changed since the market authorization of the orphan product.

For any product candidate for which we may be granted orphan drug designation in a particular indication, it is possible that another company also holding orphan drug designation for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. Even if we are the first to obtain marketing authorization for an orphan drug indication in the United States, there are circumstances under which a competing product may be approved for the same indication during the seven-year period of marketing exclusivity, such as if the later product is shown to be clinically superior to our orphan product, or if the later product is deemed a different product than ours. Further, the seven-year marketing exclusivity would not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation, or for the use of other types of products in the same indications as our orphan product.

We may be subject to certain regulations, including federal and state healthcare fraud and abuse laws, physician payment transparency laws, anti-bribery and anti-corruption laws and health information privacy and security laws. Any actual or perceived failure to comply with these regulations could have a material adverse effect on our business and financial condition.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be subject to various federal and state healthcare laws, including, without limitation, fraud and abuse laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. These laws may impact, among other things, our proposed sales, marketing and education programs. Additionally, we may be subject to state and foreign equivalents of such healthcare laws and regulations, some of which may be broader in scope and may apply regardless of the payor, as well as patient privacy regulation by both the federal government and the

states in which we conduct our business. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge and may not comply under one or more of such laws, regulations, and guidance. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other healthcare providers are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), and imprisonment, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. See section entitled "*Business - Government Regulation – Other Healthcare Laws and Compliance Requirements*."

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and individual imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or individual imprisonment.

Risks Related to Our Reliance on Third Parties

We are, and expect to continue to be, dependent on third parties to conduct some or all aspects of manufacturing of our product candidates for use in clinical trials and for commercial sale, if approved. Our business could be harmed if those third parties fail to perform satisfactorily.

We currently rely, and expect to continue to rely, on third parties to manufacture our product candidates, or certain components required for the manufacture of our product candidates, for use in conducting clinical trials and for commercial sale upon approval of any of our product candidates.

Reliance on third parties for manufacture of our product candidates and components utilized in manufacturing our product candidates entails certain risks, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third-party manufacturer does not maintain the financial, personnel or other resources to meet its obligations, the possibility that the third party fails to manufacture such components, or our product candidates or any products we may eventually commercialize, in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know-how, and the possibility of termination of our manufacturing relationship by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP, cGTP and similar jurisdictional standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretations and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards.

In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to a particular 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 if needed, or we may be unable to transfer such skills at all. In addition, if we are required to change contract manufacturers 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 candidate 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. 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 produced by different manufacturers, which could require the conduct of additional clinical trials.

Further, we depend in some instances on third party suppliers, including sole source suppliers, for the provision of reagents, materials, devices and equipment that are used by us and our third-party contract manufacturers in the production of our product candidates, including certain of our iPSC-derived cell therapy product candidates. Any disruption to or loss of supply from any of these suppliers could delay our clinical development and commercialization efforts, which would adversely affect our business, prospects, results of operations and financial condition.

We depend on strategic partnerships and collaboration arrangements, such as our collaboration arrangements with Janssen and Ono, for the development and commercialization of certain of our product candidates in certain indications or geographic territories, and if these arrangements are unsuccessful, this could result in delays and other obstacles in the development, manufacture or commercialization of any of our product candidates and materially harm our results of operations.

Our strategy for fully developing and commercializing our product candidates is dependent upon maintaining our current arrangements and establishing new arrangements with research collaborators, corporate collaborators and other third parties. We currently have corporate collaboration agreements with Janssen and Ono. These corporate collaboration agreements provide for, among other things, research funding and significant future payments should certain development, regulatory and commercial milestones be achieved. Under these arrangements, our corporate collaborators are typically responsible for:

- electing to advance product candidates through preclinical and into clinical development;
- conducting clinical development and obtaining required regulatory approvals for product candidates; and
- commercializing any resulting products.

As a result, we may not be able to conduct these corporate collaborations in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations.

This lack of control over the research funding for, and the development and commercialization of, certain of our product candidates could cause delays or other difficulties in the development and commercialization of any of our product candidates, which may prevent completion of research and development activities and intended regulatory filings in a timely fashion, if at all. Because we expect to continue to rely on our current corporate collaborators and to enter into new collaborations in the future, the development and commercialization of any of our product candidates could be substantially delayed, and our ability to receive future funding could be substantially impaired if one or more of our current or future collaborators:

- shifts its priorities and resources away from our collaborations due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- ceases development in therapeutic areas which are the subject of our collaboration;
- fails to select a product candidate for advancement into preclinical development, clinical development, or subsequent clinical development into a marketed product;
- changes the success criteria for a particular product candidate, thereby delaying or ceasing development of such product candidate;
- significantly delays the initiation or conduct of certain activities which could delay our receipt of milestone payments tied to such activities, thereby impacting our ability to fund our own activities;
- develops a product candidate that competes, either directly or indirectly, with our product candidates;
- does not obtain the requisite regulatory approval of a product candidate;
- does not successfully commercialize a product candidate;
- encounters regulatory, resource or quality issues and be unable to meet demand requirements;
- exercises its rights under the agreement to terminate the collaboration, or otherwise withdraws support for, or otherwise impairs development under the collaboration;

- disagrees on the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments or termination of such product candidate; and
- uses our proprietary information or intellectual property in such a way as to jeopardize our rights in such property.

In addition, the termination of the Janssen Agreement or the Ono Agreement or any future strategic partnership or collaboration arrangement that we enter into may prevent us from receiving any milestone, royalty payment, sharing of profits, and other benefits under such agreement. Furthermore, disagreements with these parties could require or result in litigation or arbitration, which would be time-consuming and expensive. Any of these events could have a material adverse effect on our ability to develop and commercialize any of our product candidates and may adversely impact our business, prospects, financial condition, and results of operations.

Cell-based therapies depend on the availability of reagents and specialized materials and equipment which in each case are required to be acceptable to the FDA and foreign regulatory agencies, and such reagents, materials, and equipment may not be available to us on acceptable terms or at all. We rely on third-party suppliers for various components, materials and equipment required for the manufacture of our product candidates and do not have supply arrangements for certain of these components.

Manufacturing our product candidates requires many reagents and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. To date, we and our CMOs have purchased equipment, materials and disposables used for the manufacture of our existing product candidates from third-party suppliers. Some of these suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. Reagents and other key materials from these suppliers may have inconsistent attributes and introduce variability into our manufactured product candidates, which may contribute to variable patient outcomes and possible adverse events. We rely on the general commercial availability of materials and equipment required for the manufacture of our product candidates, and do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Even if we are able to enter into such contracts, we may be limited to a sole third-party for the supply of certain required components and equipment. As a result of the ongoing COVID-19 pandemic, the business and operations of our suppliers may be disrupted or delayed, and we in turn may experience disruptions or delays in our supply chain. A delay or inability to continue to source product from any of these suppliers, which could be due to the impacts of the COVID-19 pandemic, regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to manufacture our product candidates and our ability to conduct clinical trials, which could significantly harm our business.

If we are required to change suppliers, or modify the components, equipment, materials or disposables used for the manufacture of our product candidates, we may be required to change our manufacturing operations or clinical trial protocols or to provide additional data to regulatory authorities in order to use any alternative components, equipment, materials or disposables, any of which could set back, delay, or increase the costs required to complete our clinical development and commercialization of our product candidates. Additionally, any such change or modification may adversely affect the safety, efficacy, stability, or potency of our product candidates, and could adversely affect our clinical development of our product candidates and harm our business.

We currently rely on third parties to conduct certain research and development activities and clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to timely develop, manufacture, obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely upon third parties, including medical institutions, clinical investigators, and CROs for the conduct of certain research and preclinical development activities, process development and manufacturing activities, and for the conduct, management, and supervision of clinical trials of our product candidates. We do not have direct control over the activities of these third parties, and may have limited influence over their actual performance. Our reliance on these third parties and CROs does not relieve us of our responsibilities to ensure that our clinical studies are conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards.

We are responsible for complying, and we are responsible for ensuring that our third-party service providers and CROs comply, with applicable GCP for conducting activities for all of our product candidates in clinical development, including conducting our clinical trials, and recording and reporting data from these trials. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators and trial sites. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with applicable GCP requirements. In addition, our registrational clinical trials must be conducted with product produced under applicable regulatory requirements.

If these third parties and CROs do not successfully carry out their contractual duties or obligations, meet expected deadlines or successfully complete activities as planned, or if the quality or accuracy of the research, preclinical development, process development, manufacturing, or clinical data they obtain is compromised due to the failure to adhere to applicable regulatory and manufacturing requirements or for other reasons, our research, preclinical development, process development and manufacturing activities, and clinical trials, and the development of our product candidates, may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Further, if our agreements with third parties or CROs are terminated for any reason, the development of our product candidates may be delayed or impaired, and we may be unable to advance our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or impaired.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our academic collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of our collaborator's or partner's support for our product candidates.

Some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of our product candidates. Any of these developments could harm our product development efforts.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property, or obtain and maintain patent protection for our technology and product candidates, other companies could develop products based on our discoveries, which may reduce demand for our products and harm our business.

Our commercial success will depend in part on our ability to obtain and maintain intellectual property protection for our product candidates, the operations used to manufacture them and the methods for using them, and also for our cell programming technology in order to prevent third parties from making, using, selling, offering to sell or importing our product candidates or otherwise exploiting our cell programming approach. The scope of patent protection in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we cannot be certain that we were the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are uncertain. We own and have exclusive licenses to patent portfolios for our product candidates and cell programming technology, although we cannot be certain that our existing patents and patent applications provide adequate protection or that any additional patents will issue to us with claims that provide adequate protection of our other product candidates. Further, we cannot predict the breadth of claims that may be enforced in our patents if we attempt to enforce them or if they are challenged in court or in other proceedings. If we are unable to secure and maintain protection for our product candidates and cell programming technology, or if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition, reexamination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices. The scope, validity or enforceability of our patents or the patents of our licensors may be challenged in such proceedings in either the courts or patent offices in the United States and abroad, and our business may be harmed if the coverage of

our patents or the patents of our licensors is narrowed, or if a patent of ours or our licensors is judged invalid or unenforceable, in any such proceedings.

We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely affect our business and operations.

Certain rights to our key technologies and product candidates, including intellectual property relating to our iPSC technology, are licensed from third parties. As a licensee of third-party intellectual property, we rely on our licensors to file and prosecute patent applications and maintain patents, and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our licensed patents, patent applications and other intellectual property rights, and we cannot be certain that such activities will result in valid and enforceable patents and other intellectual property rights. Additionally, our licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and we cannot be certain that our licensors will allocate sufficient resources or prioritize enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business.

If we fail to comply with our obligations under our license agreements, we could lose rights to our product candidates or key technologies.

We have obtained rights to develop, market and sell some of our product candidates through intellectual property license agreements with third parties. These license agreements impose various diligence, milestone payment, royalty and other obligations on us. In particular, under our Amended and Restated Exclusive License Agreement dated May 15, 2018 (the Amended MSK License) with Memorial Sloan Kettering Cancer Center (MSK), in the event a licensed product achieves a specified clinical milestone, MSK is eligible to receive from us certain milestone payments totaling up to $75.0 million based on the price of our common stock, where the amount of such payments owed to MSK is contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone. If we fail to comply with our obligations under our license agreements, including any payment obligations, we could lose some or all of our rights to develop, market and sell products covered by these licenses, and our ability to form collaborations or partnerships may be impaired. In addition, disputes may arise under our license agreements with third parties, which could prevent or impair our ability to maintain our current licensing arrangements on acceptable terms and to develop and commercialize the affected product candidates.

We may be involved in litigation or other proceedings relating to the enforcement or defense of patent and other intellectual property rights, which could cause us to divert our resources and could put our intellectual property at risk.

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. In addition to patent infringement lawsuits, we may be required to file interferences, oppositions, *ex parte* reexaminations, post-grant review, or *inter partes* review proceedings before the U.S. Patent and Trademark Office (the USPTO) and corresponding foreign patent offices. Litigation and other proceedings relating to intellectual property are unpredictable and expensive, and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in any such proceeding. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for research, development, and other activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings or may be required to divert such resources from our ongoing and planned research and development activities. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing or misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There also is a risk that a court or patent office in such proceeding will decide that our patents or the patents of our licensors are not valid or are not enforceable, and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party’s activities do not infringe our rights to such patents. If we were not successful in defending our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.

We or our strategic partners may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing, or increase the costs of commercializing, our product candidates.

Our success will depend, in part, on our ability to operate without infringing the proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, *ex parte* reexaminations, post-grant review, and *inter partes* review proceedings before the USPTO and corresponding foreign patent offices. 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 product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

We cannot be certain that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We cannot guarantee that the manufacture, use or marketing of our existing product candidates or any other product candidates that we develop, or the use of our cell programming technology, will not infringe third-party patents. There may be third-party patents or patent applications with claims to materials, cell compositions, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Our competitors may have filed, and may in the future file, patent applications covering products and technologies similar to ours. 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.

Third parties asserting their patent or other intellectual property rights 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 or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, cause development delays, 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 on a cost-effective basis or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for development or manufacture of our product candidates which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We own or license from third parties certain intellectual property rights necessary to develop and manufacture our product candidates. The growth of our business will likely depend in part on our ability to acquire or in-license additional proprietary rights, including to advance our research or allow commercialization of our product candidates. In that event, we may be required to expend considerable time and resources to develop or license replacement technology. For example, our programs may involve additional technologies or product candidates that may require the use of additional proprietary rights held by third parties. Furthermore, other pharmaceutical or biotechnology companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our product candidates. We may be unable to acquire or in-license any relevant third-party intellectual property rights, including any such intellectual property rights required to manufacture, use or sell our product candidates, that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, and as a result we may be unable to develop or commercialize the affected product candidates, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to

develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors' access to the same technologies licensed to us.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that 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 larger size and cash resources or greater clinical development and commercialization capabilities. In addition, it may be more costly for us to secure and maintain the necessary patent protection to block third parties from using our technology than to negotiate out-licenses or similar agreements with these parties to provide them with limited rights to use our technology. There can be no assurance that we will be able to successfully complete any such negotiations and ultimately acquire or maintain, on commercially viable terms, the rights to the intellectual property required for the successful development and commercialization of our product candidates.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and

- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets.

In conducting our business operations, we have obtained confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or other parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

We may 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. If we fail in defending any such claims, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. We may also be subject to monetary damages, and any of these outcomes could have a material adverse impact on our business.

Proprietary information and invention assignment agreements with our employees and third parties may not prevent unauthorized disclosure of our trade secrets and other proprietary information.

In addition to the protection afforded by patents, we also rely upon unpatented trade secrets and improvements, proprietary know-how, and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with our collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our collaborators and consultants. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets, however, may be difficult to protect, and any disclosure, either intentional or unintentional, by our employees or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by 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.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or

other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with any products that we may develop and commercialize, 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 biotechnology and pharmaceutical 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, whether or not successful, 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 we develop or license.

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

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. 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.

The term of our patents may not be sufficient to effectively protect our market position and products.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Even if we obtain patents covering our product candidates, once the patent life has expired for a product, we may be open to competition from other products. If the lives of our patents are not sufficient to effectively protect our products and business, our business and results of operations will be adversely affected.

Risks Related to the Commercialization of Our Product Candidates

We do not have experience marketing any product candidates and do not have a sales force or distribution capabilities, and if our products are approved we may be unable to commercialize them successfully.

We currently have no experience in marketing and selling therapeutic products. If any of our product candidates are approved for marketing, we intend to establish marketing and sales capabilities internally or we may selectively seek to enter into partnerships with other entities to utilize their marketing and distribution capabilities. If we are unable to develop adequate marketing and sales capabilities on our own or effectively partner with third parties, our ability to generate product revenues will suffer.

The commercial success of our product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payers and others in the medical community.

The commercial success of our products, if approved for marketing, will depend in part on the medical community, patients and third-party payers accepting our product candidates as effective and safe. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our products, if approved for marketing, will depend on a number of factors, including:

- the safety and efficacy of the products, and advantages over alternative treatments;
- the labeling of any approved product;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product’s approved labeling;

- the emergence, and timing of market introduction, of competitive products;
- the effectiveness of our marketing strategy; and
- sufficient third-party insurance coverage or governmental reimbursement, which may depend on our ability to provide compelling evidence that a product meaningfully improves health outcomes to support such insurance coverage or reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Any failure to achieve market acceptance for our product candidates will harm our business, results and financial condition.

We expect to face uncertainty regarding the pricing of our existing product candidates and any other product candidates that we may develop. If pricing policies for our product candidates are unfavorable, our commercial success will be impaired.

Due to the novel nature of our cellular immunotherapy product candidates, we face significant uncertainty as to the pricing of any such products for which we may receive marketing approval. While we anticipate that pricing for any cellular immunotherapy product candidates that we develop will be relatively high due to their anticipated use in the prevention or treatment of life-threatening diseases where therapeutic options are limited, the biopharmaceutical industry has recently experienced significant pricing pressures. In particular, drug pricing and other healthcare costs continue to be subject to intense political and societal pressures, which we anticipate will continue and escalate on a global basis. These pressures may result in harm to our business and reputation, cause our stock price to decline or experience periods of volatility and adversely affect results of operations and our ability to raise funds.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our product revenues.

Our ability to commercialize any of our product candidates successfully will depend in part on the availability of coverage and reimbursement for these products from third-party payors, including government health administration authorities, private health insurers, and other managed care organizations. The availability and extent of reimbursement by governmental and private payors is essential for most patients who generally rely on third-party payors to reimburse all or part of the costs of their care, including treatments such as cellular immunotherapy. Because our product candidates represent new approaches to the treatment of cancer, there is significant uncertainty as to the insurance coverage and reimbursement status of any product candidates for which we may receive regulatory approval. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors tend to follow CMS determinations to a substantial degree. If reimbursement or insurance coverage is not available for our product candidates, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be sufficient to allow us to establish or maintain pricing to generate income. Factors payors consider in determining reimbursement are based on whether the product is: (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational. See section entitled "*Business - Government Regulation – Coverage and Reimbursement*."

In addition, reimbursement agencies in foreign jurisdictions may be more conservative than those in the United States. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Failure to obtain or maintain adequate reimbursement for any products for which we receive marketing approval will adversely affect our ability to achieve commercial success, and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

Additionally, net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. 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. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

If the market opportunities for our product candidates are smaller than we believe they are, our revenues may be adversely affected and our business may suffer. Because the target patient populations of our product candidates are small, we must be able to successfully identify patients and capture a significant market share to achieve and maintain profitability.

We focus our research and development on product candidates for rare diseases, including cancer. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. These estimates may prove to be incorrect, and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe and elsewhere may turn out to be lower than expected or may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Additionally, because our target patient populations are small, we will be required to capture a significant market share to achieve and maintain profitability.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States 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 our ability to profitably sell any product candidates for which we obtain marketing approval. See section entitled "*Business - Government Regulation – Healthcare Reform and Other Regulatory Changes*."

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical and biologics pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in various congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

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

Additional changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges and fraud and abuse and enforcement. Continued implementation of the ACA and the passage of additional laws and regulations may result in the expansion of new programs such as Medicare payment for performance initiatives, and may impact existing government healthcare programs, such as by improving the physician quality reporting system and feedback program.

For each state that does not choose to expand its Medicaid program, there likely will be fewer insured patients overall, which could impact the sales, business and financial condition of manufacturers of branded prescription drugs. Where patients receive insurance coverage under any of the new options made available through the ACA, the possibility exists that manufacturers may be required to pay Medicaid rebates on that resulting drug utilization, a decision that could impact manufacturer revenues. The U.S. federal government also has announced delays in the implementation of key provisions of the ACA. The implications of these delays for our and our partners' business and financial condition, if any, are not yet clear.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures,

and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Risks Related to Our Business and Industry

The success of our existing product candidates is substantially dependent on developments within the field of cellular immunotherapy, and specifically developments relating to the use of pluripotent or genome edited cells for the manufacture of cellular therapeutics, some of which are beyond our control.

Our product candidates are designed and are being developed as therapeutic entities for use as cellular immunotherapies, and all of our current product candidates are based on our novel iPSC platform. Additionally, some of our product candidates utilize novel genome editing technologies. To date, there is limited clinical trial experience testing iPSC-derived therapeutic product candidates and genome edited therapeutics. The fields of cellular and genome edited therapies are evolving, and as more therapeutic product candidates derived from pluripotent and genome edited cells are reviewed by regulatory authorities, regulatory authorities may impose additional requirements for approval that were not previously anticipated. There have also been several significant adverse events from gene therapy treatments in the past, including reported cases of leukemia and death. There can be no assurance that any product candidates developed from or related to our iPSC platform or any of our research programs will not cause severe or undesirable side effects or result in significant delays or unanticipated costs, or that such development problems can be solved. Any adverse developments in the fields of cellular immunotherapy or genome edited therapy will negatively affect our ability to develop and commercialize our product candidates.

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

The biotechnology and pharmaceutical industries, and the immune-oncology industry specifically, are intensely competitive and characterized by rapid and significant innovation. We face competition from biotechnology and pharmaceutical companies, universities, and other research institutions, and many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations and facilities. In particular, there are several companies and institutions developing products that may be competitive to our iPSC-derived product candidates or candidates in our research and development pipeline, or may render our product candidates obsolete or noncompetitive. Should one or more of these products be successful, the market for our products may be reduced or eliminated, and we may not achieve commercial success. For additional information regarding our competition, see “Item 1. Business—Competition” in our Annual Report.

The loss of any member of our senior management team or our inability to attract and retain key personnel and consultants could adversely affect our business.

We may not be able to retain or attract qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for a limited number of qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. The loss of any members of our senior management team could adversely impact our operations if we experience difficulties in recruiting and hiring qualified successors. We may also experience difficulties in attracting or retaining personnel with sufficient experience and skills in the complex and emerging field of cellular therapeutic development and manufacture to support our ongoing and planned clinical development activities. Many of the biotechnology and pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources and different risk profiles than we do. We may be required to provide compensation in excess of historical levels in order to recruit and retain personnel in the current market. If we are not able to retain and attract necessary personnel and consultants to perform the requisite operational roles and accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We expect to continue to expand our development and manufacturing operations, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We are experiencing rapid growth and as of December 31, 2021, we had 449 employees. We expect continued growth in the number of our employees and the scope of our operations, particularly to continue our clinical and research operations, and to expand our regulatory, quality, and manufacturing operations. This expected growth may place a strain on our administrative and operational

infrastructure, and managing this growth may impose significant added responsibilities on members of management and divert a substantial amount of attention from day-to-day activities.

To manage our anticipated future growth, we will continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the complexity in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Any inability to manage our expected growth and the expansion of our operations may result in loss of business opportunities, loss of employees and reduced productivity among remaining employees, weaknesses in our infrastructure, and operational mistakes, including in the operation and qualification of our GMP manufacturing operations and facility, and could delay the execution of our business plans or disrupt our operations. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

The global COVID-19 pandemic could adversely impact various aspects of our business, results of operations and financial condition.

The COVID-19 pandemic has dramatically impacted the global health and economic environment, including millions of confirmed cases and deaths, business slowdowns or shutdowns, labor shortages, supply chain challenges, changes in government requirements, regulatory challenges, inflationary pressures and market volatility. Although we have, to date, managed to continue most of our operations, we cannot predict the future course of events nor can we assure that this global pandemic, including its economic impact, will not have a material adverse impact on our business, results of operations and financial condition.

As a result of the ongoing COVID-19 pandemic, various aspects of our business operations have been, and could continue to be, disrupted. The pandemic likely will continue to impact our workforce, including impacts on staffing levels (as a result of illnesses, quarantine, isolation and absenteeism), adjusted work locations and schedules and access to our facilities. The pandemic may require us to continue to take extraordinary measures to protect the health and well-being of our employees. For example, since the start of the pandemic we have implemented a range of health and safety measures, which have included, at various times, imposing onsite occupancy limits, restricting on-site staff to only those required to execute certain laboratory, manufacturing and related support activities, and requiring self-health testing prior to coming onsite.

The increase in working remotely could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, and clinical trial sites. If our on-site staff conducting research and development, preclinical studies, and manufacturing activities are not able to access our laboratories or manufacturing space, whether due to quarantine/isolation orders, travel restrictions or other government restrictions, these core activities may be significantly limited or curtailed, possibly for an extended period of time, which could impair our ability to complete IND-enabling studies or select future development candidates. Our business operations may be further disrupted if our manufacturing facility becomes subject to a viral contamination requiring a suspension of manufacturing activities, or if any of our employees, officers or directors, or their respective personal or business contacts, contract an illness related to COVID-19, including new variants of the virus, that renders them unable to perform their duties as a result.

The macroeconomic impacts of the pandemic, including a tightened labor market and evolving government requirements, including those related to vaccinations, will also likely continue to affect our company. They may further affect our ability to hire, develop and retain our talented and diverse workforce, to maintain performance levels, and to maintain our corporate culture. We expect to continue to incur additional costs as a result of the COVID-19 pandemic, including to protect the health and well-being of our employees and to respond to government requirements, which costs we may not be fully able to recover.

The pandemic has impacted and may continue to impact the company’s supply chains. If our suppliers have increased challenges with their workforce (including as a result of illness, absenteeism, reactions to health and safety or government requirements), facility closures, timely access to necessary components, materials and other supplies at reasonable prices, access to capital, and access to fundamental support services (such as shipping and transportation), they may be unable to provide the agreed-upon goods and services in a timely, compliant and cost-effective manner. We have incurred and may in the future incur additional costs and delays in our business, including as a result of higher prices, schedule delays or the need to identify and develop alternative suppliers.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through equity or debt financings, or such financing transactions may be on unfavorable terms. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruptions and uncertainties in global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition,

a recession, depression or other sustained adverse market event resulting from the spread of COVID-19, including new variants of the virus, could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. For example, the emergence of the Delta and Omicron variants in 2021 significantly impacted rates of infection and prompted public health officials to reconsider certain health and safety measures that had been adopted to date, including vaccination requirements, guidance around quarantine and isolation periods, and mask wearing. We do not yet know the full extent of potential delays or impacts on our business, our clinical and preclinical programs, our research, manufacturing, and regulatory activities, healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on our operations, and we will continue to monitor the situation closely.

If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time, we have considered, and we will consider in the future, strategic business initiatives intended to further the expansion and development of our business. These initiatives may include acquiring businesses, technologies or products or entering into business combinations with other companies. If we pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources to integrate new businesses, technologies and products;
- assume substantial actual or contingent liabilities;
- reprioritize our development programs and even cease development and commercialization of our product candidates; or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company on terms that certain of our stockholders may not deem desirable.

Although we intend to evaluate and consider acquisitions, reorganizations and business combinations in the future, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

We face potential product liability exposure far in excess of our limited insurance coverage.

The use of our product candidates in clinical trials, and the sale of any products for which we obtain marketing approval, exposes us to the risk of product liability claims. Product liability claims might be brought against us by participants in clinical trials, hospitals, medical centers, healthcare providers, pharmaceutical companies, and consumers, or by others selling, manufacturing or otherwise coming into contact with our product candidates. We carry product liability insurance and we believe our product liability insurance coverage is sufficient in light of our current clinical programs. In addition, if and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain insurance coverage for any approved products on commercially reasonable terms or in sufficient amounts to protect us against losses due to liability.

On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. In addition, under some of our agreements with clinical trial sites, we are required to indemnify the sites and their personnel against product liability and other claims. A successful product liability claim, or a series of claims, brought against us or any third parties whom we are required to indemnify could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for a variety of reasons. Such events, whether or not resulting from our product candidates, could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively affect or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our development and commercialization efforts, delay our regulatory approval process, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Our insurance policies are expensive and protect us from only some risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk to which our business is or may be exposed. Some of the policies we maintain include general liability, product liability, property, employee benefits liability, employment practices, workers' compensation, cyber, directors' and officers' insurance, and umbrella. We do not know, however, if we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Even if we obtain insurance, a claim could exceed the amount of our insurance coverage or it may be excluded from coverage under the terms of the policy. Further, insurance coverage may not be available or successfully secured for loss profits or business interruption relating to the COVID-19 pandemic and its impacts. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA or foreign regulators, to provide accurate information to the FDA or foreign regulators, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. Employee and independent contractor misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. If any actions alleging such conduct are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant effect on our business, including the imposition of significant fines or other sanctions.

We face risks of potential liability related to the privacy of personal information, including health information we utilize in the development of our products, as well as information we obtain from clinical trials sponsored by us from research institutions and directly from individuals.

We and our partners and vendors may be subject to various federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators, including the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and privacy and security requirements under HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute a violation of the Federal Trade Commission Act. In addition, certain of the materials we use as starting material in our iPSC-derived product candidates are derived from human sources, which potentially contain sensitive identifiable personal information regarding the donor. In addition, in conducting our clinical trials, we may maintain sensitive identifiable personal information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our clinical trials. As such, we may become subject to further obligations under HIPAA. Our collection of personal information generally (e.g., of employees currently and/or of patients in the future) may subject us to state data privacy laws governing the processing of personal information and requiring notification of affected individuals and state regulators in the event of a breach of such personal information. These state laws include the California Consumer Privacy Act (CCPA) and its related regulations, and (once effective) the California Privacy Rights Act (CPRA) amending the CCPA, which establish additional data privacy rights for residents of the State of California, with corresponding obligations on businesses related to transparency, deletion rights, and opt-out of the selling of personal information, and grants a private right of action for individuals in the event of certain security breaches. Similar laws relating to data privacy and security have been proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging, require us to expend significant resources to come into compliance, and restrict our ability to process certain personal information.

Certain state laws may be more stringent or broader in scope than the CPRA, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts.

We are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable data privacy and security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, and could result in adverse publicity that could harm our business. Moreover, even if we take all necessary action to comply with legal and regulatory requirements, we could be subject to a data breach or other unauthorized access of personal information, which could subject us to fines and penalties, as well as litigation and reputational damage. If we fail to keep apprised of and comply with applicable international, federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to seek to commercialize our clinical candidates. Any threatened or actual government enforcement action or litigation where private rights of action are available could also generate adverse publicity, damage our reputation, result in liabilities, fines and loss of business, and require that we devote substantial resources that could otherwise be used in other aspects of our business.

We make public statements about our use and disclosure of personal information through our privacy policy information provided on our internet platform and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or contractual partners fail to comply with our published policies, certifications and documentation. The publication of our privacy policy and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any failure, real or perceived, by us to comply with our posted privacy policies or with any legal or regulatory requirements, standards, certifications or orders or other privacy or consumer protection-related laws and regulations applicable to us could cause our customers to reduce their use of our products and services and could materially and adversely affect our business, financial condition and results of operations. In many jurisdictions, enforcement actions and consequences for non-compliance can be significant and are rising. In addition, from time to time, concerns may be expressed about whether our products, services or processes compromise the privacy of customers and others. Concerns about our practices with regard to the collection, use, retention, security, disclosure, transfer and other processing of personal information or other privacy-related matters, even if unfounded, could damage our reputation and materially and adversely affect our business, financial condition and results of operations.

Many statutory requirements, both in the United States and abroad, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 U.S. states and the District of Columbia require businesses to provide notice to consumers whose sensitive personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify customers or other counterparties of a security breach. Although we may have contractual protections with our third-party service providers, contractors and consultants, any actual or perceived security breach could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

In addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded in a manner that requires changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with contract partners and the physician and patient community and have a material and adverse impact on our business.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors, vendors, and consultants may be vulnerable to damage from cyber risks, including attempts to gain unauthorized access to and to harm sensitive information and networks, insider threats, and ransomware. These vulnerabilities may be heightened as a result of remote work policies implemented by us and our third-party contractors in response to the COVID-19 pandemic.

We have from time to time experienced, and may continue to experience in the future, cyber-attacks on our information technology systems despite our best efforts to prevent them. Although such breaches have been immaterial to our business to date, investigations into and remedial efforts in connection with any breaches, even those with immaterial impact, can be costly and time-consuming, and any future breaches could be material, or cause significant disruption, to our business. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for research and development, the manufacture and supply of drug product and drug substance and to conduct clinical trials. We depend on these third parties to implement adequate controls and safeguards to protect against and report cyber incidents. If they fail to do so, we may suffer financial and other harm, including to our information, operations, performance, and reputation. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, 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.

Cyber threats, both on premises and in the cloud, are evolving and include, but are not limited to: malicious software, destructive malware, ransomware, attempts to gain unauthorized access to systems or data, disruption to operations, critical systems or denial of service attacks; unauthorized release of confidential, personal or otherwise protected information; corruption of data, networks or systems; harm to individuals; and loss of assets. In addition, we could be impacted by cyber threats or other disruptions or vulnerabilities found in products or services we use that are provided to us by third-parties. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. These events, if not prevented or effectively mitigated, could damage our reputation, require remedial actions and lead to loss of business, regulatory actions, potential liability and other financial losses.

Certain data breaches must also be reported to affected individuals and various government and/or regulatory agencies, and in some cases to the media, under provisions of HIPAA, as amended by HITECH, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the European Union Data Protection Directive, and financial penalties may also apply.

Our insurance policies may not be adequate to compensate us for the potential losses arising from breaches, failures or disruptions of our infrastructure, catastrophic events and disasters or otherwise. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly and divert management's attention.

Furthermore, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could 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, 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 of these factors. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and 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 product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical 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. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Financial Condition and the Ownership of Our Common Stock

Our ongoing and planned operations, including the development of our product candidates, will require substantial additional funding, without which we will be unable to complete preclinical or clinical development of, or obtain regulatory approval for, our product candidates.

We are currently advancing multiple product candidates through clinical development, and conducting preclinical research and development activities in our other programs. Drug development is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our current product candidates in clinical trials and seek to initiate clinical development for additional product candidates.

As of December 31, 2021, our cash and cash equivalents and investments were $716.6 million. We intend to use our cash and cash equivalents and investments primarily to fund the advancement and clinical development of our current product candidates and our ongoing preclinical, discovery and research programs, and for working capital and general corporate purposes. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic and licensing arrangements or a combination of these approaches. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize our existing product candidates and any other product candidates we may identify and develop. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our future capital requirements will depend on many factors, including, but not limited to:

- the progress, results, size, timing and costs of our ongoing and planned clinical trials, and any additional clinical trials we may initiate, conduct or support for our product candidates;
- the progress, results, size, timing and costs of our preclinical, process development and manufacturing studies, and activities necessary to initiate and conduct clinical trials for our product candidates and to establish and maintain manufacturing capabilities necessary to support such trials;
- continued progress in our research and development programs, including preclinical studies, process development, manufacturing and other research activities that may be necessary in order for an IND application to go into effect for a prospective clinical development candidate, as well as potential future clinical trials of any additional product candidates we may identify for development;
- the extent to which we are required to pay milestone or other payments under our existing in-license agreements and any in-license agreements that we may enter into in the future, and the timing of such payments, including payments owed to Memorial Sloan-Kettering in connection with the stock price appreciation milestones;
- our ability and the ability of our investigators to initiate and conduct, and the progress, results, size, timing and costs of, clinical trials of our product candidates that will be necessary to support any application for regulatory approval;
- our ability to manufacture, or enter into arrangements with third parties for the manufacture of our existing product candidates, as well as potential future clinical development candidates, both for clinical development and commercialization, and the timing and costs associated with such manufacture;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, or other costs we may incur, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the cost of manufacturing, distribution, and commercialization activities and arrangements, including the manufacturing of our product candidates, establishment of effective protocols for the supply and transport of our product candidates, and the establishment of a sales and marketing organization either internally or in partnership with a third party; and
- our ability to establish and maintain strategic arrangements and alliances with third-party collaborators including our existing collaborations with Janssen Biotech, Inc., Ono Pharmaceutical Co., Ltd., the University of Minnesota, and Memorial Sloan Kettering, to advance the research, development and commercialization of therapeutic products.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or

license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at a different stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. In addition, while the overall impact of the COVID-19 pandemic on the global economy is currently unknown and difficult to predict, the pandemic has caused significant disruptions and created uncertainties in the global financial markets, and the economic impacts of the pandemic could materially and adversely affect our ability to raise capital through equity or debt financings in the future.

If we cannot raise additional capital or obtain adequate funds, we may be required to curtail significantly our research and clinical programs or may not be able to continue our research or clinical development of our product candidates. Our failure to raise additional capital, or obtain adequate funds, will have a material adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

We have a limited operating history, have incurred significant losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company formed in 2007 with a limited operating history. We have not yet obtained regulatory approval for any of our product candidates or generated any revenues from therapeutic product sales. Since inception, we have incurred significant net losses in each year and, as of December 31, 2021, we had an accumulated deficit of $769.1 million. We expect to continue to incur losses for the foreseeable future as we continue to fund our ongoing and planned clinical trials of our product candidates, and our other ongoing and planned research and development activities. We also expect to incur significant operating and capital expenditures as we continue our research and development of, and seek regulatory approval for, our product candidates, in-license or acquire new product candidates for development, implement additional infrastructure and internal systems, and hire additional scientific, clinical, and administrative personnel. We anticipate that our net losses for the next several years could be significant as we conduct our planned operations.

Because of the numerous risks and uncertainties associated with pharmaceutical, biological, and cell therapy product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA, or comparable foreign regulatory authorities, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials, preclinical studies, process development, manufacturing activities, or the research and development of any of our product candidates. The amount of our future net losses will depend, in part, on the rate of increase in our expenses, our ability to generate revenues and our ability to raise additional capital. These net losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Our stock price is subject to fluctuation based on a variety of factors.

The market price of shares of our common stock could be subject to wide fluctuations as a result of many risks listed in this section, and other risks beyond our control, including:

- the timing of the initiation of, and progress in, our current and planned clinical trials;
- the results of our clinical trials and preclinical studies, and the results of clinical trials and preclinical studies by others for product candidates or indications similar to ours;
- developments related to the FDA or to regulations applicable to cellular immunotherapies generally or our product candidates in particular including, but not limited to, regulatory pathways and clinical trial requirements for approvals;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments related to proprietary rights including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key management or scientific personnel;
- actual or anticipated changes in our research and development activities and our business prospects, including in relation to our competitors;
- developments of technological innovations or new therapeutic products by us or others in the field of immunotherapy;
- announcements or expectations of additional equity or debt financing efforts;
- sales of our common stock by us or by our insiders or our other stockholders;

- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- comments by securities analysts;
- fluctuations in our operating results (including changes related to stock-based compensation from performance-based awards); and
- general economic and market conditions.

These and other market and industry factors, including the effects of the COVID-19 pandemic on the global economy, may cause the market price and demand for our common stock to fluctuate substantially regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock.

Changes in our stock price may also trigger financial obligations under our licensing arrangements. For example, pursuant to the terms of our license agreement with MSK, MSK is eligible to receive from us certain milestone payments totaling up to $75.0 million based on the price of our common stock, where the amount of such payments owed to MSK is contingent upon certain increases in the price of our common stock following the date of achievement of a specified clinical milestone. In July 2021, we achieved the specified clinical milestone for a licensed product under our license agreement with MSK and our ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. Accordingly, MSK received the first milestone payment of $20.0 million in November 2021; however, uncertainty of the price of our common stock results in an inability to ascertain the precise timing of any remaining future milestone payments in advance.

Our principal stockholders and management own a significant percentage of our stock and may be able to exercise significant control over our company.

As of February 17, 2022, our executive officers, directors and entities affiliated with our five percent stockholders beneficially own, in the aggregate, shares representing approximately 42.6% of our outstanding voting stock. If, in accordance with the CoD (as such term is defined in Note 9 of the notes to the consolidated financial statements herewith) relating to the Class A Convertible Preferred Stock, Redmile (as such term is defined in Note 9 of the notes to the consolidated financial statements herewith) elects to remove certain limitations on the percentage of the our outstanding common stock that it may own such that the 2,794,549 shares of Class A Convertible Preferred Stock currently held by Redmile become fully convertible at Redmile's option into 13,972,745 shares of common stock, the beneficial ownership of our executive officers, directors and entities affiliated with our five percent stockholders would increase to 49.6%. Although we are not aware of any voting arrangements in place among these stockholders, if these stockholders were to choose to act together, as a result of their stock ownership, they would be able to influence our management and affairs and control all matters submitted to our stockholders for approval, including the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership may have the effect of delaying or preventing a change in control of our company that our other stockholders may believe are in their best interests, or adversely affecting the liquidity, volatility, and market price of our common stock. For example, if any of our directors, executive officers or other entities affiliated with our five percent stockholders elect to sell, transfer or otherwise dispose of a significant amount of shares of our common stock, this could result in a decrease in our stock price. Furthermore, any transferees or successors of all or a significant portion of our existing stockholders' ownership in us will be able to exert a similar amount of control over us through their ownership position.

We may sell additional equity or debt securities or enter into other arrangements to fund our operations, which may result in dilution to our stockholders and impose restrictions or limitations on our business.

We expect that significant additional capital will be needed in the future to continue our planned operations, and we may seek additional funding through a combination of equity offerings, debt financings, state or government grants, strategic alliances, licensing and collaboration arrangements, or other third-party business arrangements. These financing activities may have an adverse effect on our stockholders' rights, the market price of our common stock and on our operations and may require us to relinquish rights to some of our technologies, intellectual property or product candidates, issue additional equity or debt securities, or otherwise agree to terms unfavorable to us. Further, in November 2021 we filed a Form S-3 pursuant to which we may issue up to $350.0 million in common stock in sales deemed to be an "at the market offering" as defined by the Securities Act of 1933, as amended (the Securities Act) and, so long as we qualify as a "well-known seasoned issuer" as defined in Rule 405 of the Securities Act, an unlimited amount of shares of our common stock, preferred stock, debt securities, warrants and/or units. Any sale or issuance of securities pursuant to a registration statement or otherwise may result in dilution to our stockholders and may cause the market price of our stock to decline, and new investors could gain rights superior to our existing stockholders. In addition, any debt financings that we may enter into in the future may impose restrictive covenants or otherwise adversely affect the holdings or the rights of our stockholders, and any additional equity financings will be dilutive to our stockholders. Furthermore, additional equity or debt financing might not be available to us on reasonable terms, if at all.

A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. A significant portion of our outstanding shares of common stock are held by a small number of stockholders, including our directors, officers and significant stockholders. Sales by our stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock.

For example, we registered all of the 5,250,000 shares of common stock issued by us in our August 2016 private placement transaction for resale on a Form S-3, which was declared effective by the SEC in September 2016. We also registered all of the 6,766,915 shares of common stock issued by us and all 14,097,745 shares of common stock issuable upon the conversion of an aggregate of 2,819,549 shares of Class A Convertible Preferred Stock issued by us in our November 2016 private placement transaction for resale on a Form S-3, which was declared effective by the SEC in January 2017. Additionally, we have registered the shares of common stock issued to Johnson & Johnson Innovation – JJDC, Inc. under a stock purchase agreement entered into in connection with the Janssen Agreement pursuant to a registration statement on Form S-3. Moreover, we registered all of the 5,380,117 shares of common stock issued by us and all of the 257,310 prefunded warrants to purchase common stock in our public offering in January 2021.

We have also registered or intend to register all shares of our common stock subject to options, restricted stock units or other equity awards issued or reserved for future issuance under our equity incentive plans. As a result, these shares will be available for sale in the public market subject to vesting arrangements and exercise of options, and restrictions under applicable securities laws. In addition, certain of our executive officers, employees and affiliates have established or may in the future establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

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

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

Provisions of Delaware law or our charter documents could delay or prevent an acquisition of our company, and could make it more difficult for you to change management.

Provisions of Delaware law, our amended and restated certificate of incorporation, and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or delay attempts by stockholders to replace or remove our current management or members of our board of directors. These provisions include:

- a classified board of directors with limitations on the removal of directors;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings;
- the ability of our board of directors to make, alter or repeal our amended and restated bylaws; and
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or discouraging a potential acquisition proposal or tender offer could limit the opportunity for our stockholders to achieve liquidity for their shares of our common stock, even if the acquisition proposal or tender offer is at a premium over the then-current market price for our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware and the U.S. federal district courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to litigate disputes with us in a different judicial forum.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, or employees to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware, our amended and restated certificate of incorporation or our amended and restated bylaws; or (iv) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision will not apply to any causes of action arising under the Securities Act. Unless we consent in writing to the selection of an alternate forum, the U.S. federal district courts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The forum selection clause in our amended and restated bylaws may limit our stockholders' ability to litigate disputes with us in a different judicial forum.

Our ability to use our net operating loss carryforwards and certain other tax benefits may be limited and, as a result, our future tax liability may increase.

As of December 31, 2021, we had federal and California net operating loss carryforwards of $289.7 million and $291.2 million, respectively, some of which begin to expire in various amounts in 2027 and 2028, respectively. As of December 31, 2021, we also had federal and California research and development tax credit carryforwards of $25.7 million and $25.8 million, respectively. The federal research and development tax credit carryforwards will begin to expire in 2035 unless previously utilized, while the California carryforwards will carry forward indefinitely. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses (NOLs) or tax credits, or NOLs or credits, to offset future taxable income or taxes. Generally, a change of more than 50 percentage points in the ownership of a corporation's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. We have determined that we triggered an ownership change limitation in November 2009 and again in May 2015. We have determined that we do not believe there were any ownership changes from May 2015 through December 2021. We have not analyzed periods subsequent to December 2021. We may experience additional ownership changes as a result of shifts in our stock ownership in the future. Limits on our ability to use our pre-change NOLs or credits to offset U.S. federal taxable income could potentially result in increased future tax liability to us if we earn net taxable income in the future. The amount of NOLs generated in taxable periods beginning after December 31, 2021, that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. U.S. federal and certain state NOLs generated in taxable years beginning after December 31, 2017 are not subject to expiration.

General Risk Factors

We could be subject to securities class action litigation.

The stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our ability to invest in and expand our business and meet our financial obligations, to attract and retain third-party contractors and collaboration partners and to raise additional capital depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic and political conditions and financial, business, regulatory and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States, political influences and inflationary pressures, and fluctuations in costs, particularly due to changes in labor costs and material costs. For example, an overall decrease in or loss of insurance coverage among individuals in the United States due to high levels of unemployment (particularly as a result of the COVID-19 pandemic), underemployment or the repeal of certain provisions of the ACA may decrease the demand for healthcare services and pharmaceuticals. Additionally, the availability of healthcare services and resources is currently constrained due to the COVID-19 pandemic. If fewer patients are seeking medical care because they do not have insurance coverage or are unable

to obtain medical care for their conditions due to resource constraints on the healthcare system, we may experience difficulties in any eventual commercialization of our product candidates and our business, results of operations, financial condition and cash flows could be adversely affected. In addition, if we are unable to manage cost fluctuations and inflationary pressures, including prices of materials, costs of labor, it may adversely impact our operating performance, expenses and results.

In addition, our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets upon which pharmaceutical and biopharmaceutical companies such as us are dependent for sources of capital. In the past, global financial crises have caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, including as a result of the COVID-19 pandemic, could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all, and weakened demand for our product candidates. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the COVID-19 pandemic, current economic climate and financial market conditions could adversely impact our business.

We or the third parties upon whom we depend may be adversely affected by earthquakes, fires, or other natural disasters, including epidemics and pandemics such as COVID-19, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes, fires, or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our manufacturing facilities or those of our CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. For example, as a result of the COVID-19 pandemic, we may experience delays or disruptions in our clinical development activities, our research and development activities, and in the supply of drug product for our clinical trials. Any continued or subsequent measures taken by governmental authorities or businesses to contain the spread of COVID-19, or the perception that such measures may be required in the future should another outbreak occur, could adversely affect our business, operations, financial condition, prospects or results of operations by restricting our ability to conduct our clinical trials and research and development activities, and limiting our and our third-party manufacturers' ability to manufacture product and forcing temporary closure of our facilities and facilities that we rely upon. The disaster recovery and business continuity plans we have in place currently are limited and may not prove adequate for protecting and continuing our business in the event that our business is disrupted as a result of the COVID-19 pandemic or other serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

If we fail to maintain an effective system of disclosure controls and procedures and internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act), and the related rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing and maintaining corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

We cannot assure that we will not have material weaknesses or significant deficiencies in our internal control over financial reporting. If we are unable to successfully remediate any material weakness or significant deficiency in our internal control over financial reporting, or identify any material weaknesses or significant deficiencies that may exist, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, and our stock price may decline materially as a result.

If we fail to comply with environmental, health, and safety laws and regulations, including regulations governing the handling, storage or disposal of hazardous materials, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our operations involve the use of hazardous materials, including chemicals, biological materials and infectious agents. Our operations also may produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us

of hazardous materials, we could be held liable for any resulting damages, 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.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Changes in tax law may adversely affect us or our investors.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, the Tax Cuts and Jobs Act, or the TCJA, was enacted in 2017 and made significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses to 80% of current year taxable income and the elimination of net operating loss carrybacks (though any such net operating losses may be carried forward indefinitely), and the modification or repeal of many business deductions and credits. Additionally, the Coronavirus Aid, Relief, and Economic Security Act, which, among other things, suspended the 80% limitation on the deduction for net operating losses in taxable years beginning before January 1, 2021, permits a 5-year carryback of net operating losses arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally caps the limitation on the deduction for net interest expense at 50% of adjusted taxable income for taxable years beginning in 2019 and 2020. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

Our business could be negatively impacted by corporate citizenship and environmental, social and corporate governance (ESG) matters and/or our reporting of such matters.

There is an increasing focus from certain investors, consumers, and other stakeholders concerning corporate citizenship and sustainability matters. We could be perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. Any such matters, or related corporate citizenship and sustainability matters, could have a material adverse effect on our business.

ITEM 1B. Unresolved Staff Comments

Not Applicable.

ITEM 2. Properties

Facilities

As of December 31, 2021, we occupied approximately 200,000 square feet of office, laboratory and GMP manufacturing space in San Diego, California under a non-cancelable operating lease through May 2036. In addition, we have additional operating leases for office and laboratory space in San Diego, California, San Francisco, California, and New York, New York. We believe that these facilities are adequate for our current needs.

ITEM 3. Legal Proceedings

We are not a party to any material legal proceedings at this time. 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, 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 effect 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

Market Information

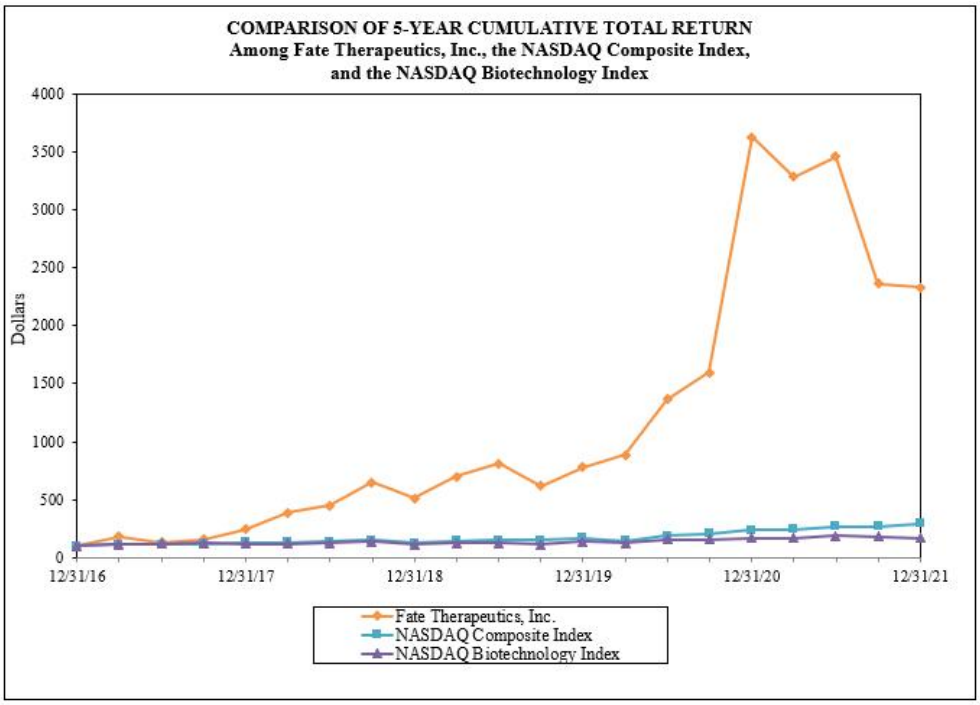
Our ticker symbol is "FATE", as traded and reported by The NASDAQ Global Market.

Holders of Common Stock

As of February 17, 2022, there were approximately 22 stockholders of record of our common stock. The approximate number of holders is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

Performance Graph

Set forth below is a graph comparing the cumulative total return on our common stock, the NASDAQ Composite® (US) Index and the NASDAQ Biotechnology Index over the five-year period ending December 31, 2021. The graph assumes that $100 was invested in our common stock and in each of the comparative indices as of the market close on December 31, 2016. The past performance of our common stock is no indication of future performance.



Dividends

We have never declared or paid any dividends on our capital or common stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

During the year ended December 31, 2021, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

We did not repurchase any securities during the year ended December 31, 2021.

ITEM 6. Selected Financial Data

Not applicable.

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 under Item 8 of this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption "Item 1A. Risk Factors."

This section of this Form 10-K generally discusses 2021 and 2020 items and year-to-year comparisons between 2021 and 2020. Discussions of 2019 items and year-to-year comparisons between 2020 and 2019 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on February 24, 2021 and incorporated herein by reference.

Overview

We are a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for patients with cancer. We are developing first-in-class cell therapy product candidates based on a simple notion: we believe that better cell therapies start with better cells.

To create better cell therapies, we use a therapeutic approach that we generally refer to as cell programming. We use human induced pluripotent stem cells (iPSCs) to generate a clonal master iPSC line having preferred biological properties, and we direct the fate of the clonal master iPSC line to create our cell therapy product candidate. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, we believe clonal master iPSC lines can be used as a renewable source for manufacturing cell therapy products which are well-defined and uniform in composition, can be repeatedly mass produced at significant scale in a cost-effective manner, and can be delivered off-the-shelf to treat many patients. Utilizing this therapeutic approach, we are advancing a pipeline of programmed cellular immunotherapies, including off-the-shelf natural killer (NK) and T-cell product candidates derived from clonal master iPSC lines for the treatment of cancer.

In September 2018, we entered into a collaboration and option agreement with Ono Pharmaceutical Co. Ltd. (Ono) for the joint development and commercialization of off-the-shelf, iPSC-derived chimeric antigen receptor (CAR) T-cell product candidates (Ono Agreement) for the treatment of cancer.

In April 2020, we entered into a collaboration and option agreement with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen Agreement), for the development and commercialization of off-the-shelf, iPSC-derived CAR NK and CAR T-cell product candidates for the treatment of cancer.

We were incorporated in Delaware in 2007, and are headquartered in San Diego, CA. Since our inception in 2007, we have devoted substantially all of our resources to our cell programming approach and the research and development of our product candidates, the creation, licensing and protection of related intellectual property, and the provision of general and administrative support for these activities. To date, we have funded our operations primarily through the public and private sale of common stock, the private placement of preferred stock and convertible notes, commercial bank debt and revenues from collaboration activities and grants.

We have never been profitable and have incurred net losses in each year since inception. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur operating losses for at least the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses will increase substantially in connection with our ongoing and planned activities as we:

- conduct our ongoing and planned clinical trials of our product candidates, which may include higher clinical trial expenses associated with arrangements we may enter into with clinical research organizations for the execution and management of certain clinical trials;
- conduct GMP production, process and scale-up development and technology transfer activities for the manufacture of our product candidates, including those undergoing clinical investigation and IND-enabling preclinical development;
- procure laboratory equipment, materials and supplies for the manufacture of our product candidates and the conduct of our research activities;
- conduct preclinical and clinical research to investigate the therapeutic activity of our product candidates;
- continue our research, development and manufacturing activities, including under our sponsored research and collaboration agreements with Janssen and Ono;

- maintain, prosecute, protect, expand and enforce our intellectual property portfolio;
- engage with regulatory authorities for the development of, and seek regulatory approvals for, our product candidates;
- establish business operations at our new corporate headquarters, including internal GMP production capabilities;
- hire additional clinical, manufacturing, regulatory, quality control and technical personnel to advance our product candidates;
- hire additional scientific personnel to advance our research and development efforts; and
- hire general and administrative personnel to continue operating as a public company and support our operations.

We do not expect to generate any meaningful product sales or royalty revenue unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will seek to fund our operations through public or private equity or debt financings or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative effect on our financial condition and ability to develop our product candidates.

Due to the global outbreak of SARS-CoV-2, the strain of coronavirus that causes Coronavirus disease 19 (COVID-19), including the emergence of new variants of the virus, we experienced impacts on certain aspects of our business, including our clinical trial and research and development activities, during the year ended December 31, 2021. For example, certain of our research and development activities have been delayed or disrupted as a result of measures we implemented in response to governmental “stay at home” orders and in the interests of public health and safety, and we have experienced delays or disruptions in the initiation and conduct of our clinical trials as a result of prioritization of hospital and other medical resources toward pandemic efforts, policies and procedures implemented at clinical sites with respect to the conduct of clinical trials, and other precautionary measures taken in treating patients or in practicing medicine in response to the ongoing COVID-19 pandemic. The scope and duration of these delays and disruptions, and the ultimate impacts of the COVID-19 pandemic on our operations, are currently unknown, and depend on continuously changing circumstances, including the emergence of new variants of the virus, such as the Delta and Omicron variants. We are continuing to actively monitor the situation and may take further precautionary and preemptive actions as may be required by federal, state or local authorities or that we determine are in the best interests of public health and safety and that of our patient community, employees, partners, and stockholders. We cannot predict the effects that such actions, or the impact of the ongoing COVID-19 pandemic, including the emergence of new variants of the virus, on global business operations and economic conditions, may have on our business, strategy, collaborations, or financial and operating results.

Financial Operations Overview

We conduct substantially all of our activities through Fate Therapeutics, Inc., a Delaware corporation, at our facilities in San Diego, California. Fate Therapeutics, Inc. owns 100% of the voting shares of Tfinity Therapeutics, Inc. (Tfinity), 100% of the voting shares of Fate Therapeutics Ltd. (Fate Ltd.), incorporated in the United Kingdom, and 100% of the voting shares of Fate Therapeutics B.V. (Fate B.V.), incorporated in the Netherlands. The following information is presented on a consolidated basis to include the accounts of Fate Therapeutics, Inc., Tfinity, Fate B.V., and Fate Ltd. To date, the aggregate operations of our subsidiaries have not been significant and all intercompany transactions and balances have been eliminated in consolidation.

Collaboration Revenue

To date, we have not generated any revenues from therapeutic product sales or royalties. Our revenues have been derived from collaboration agreements and government grants.

Agreement with Janssen Biotech, Inc.

On April 2, 2020 (the Janssen Agreement Effective Date), we entered into a Collaboration and Option Agreement (the Janssen Agreement) with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Additionally, on the Janssen Agreement Effective Date, we entered into a Stock Purchase Agreement (the Stock Purchase Agreement) with Johnson & Johnson Innovation - JJDC, Inc. (JJDC). Under the terms of the Janssen Agreement and the Stock Purchase Agreement taken together, we received $100.0 million, of which $50.0 million was an upfront cash payment and $50.0 million was in the form of an equity investment by JJDC. Additionally, we are entitled to receive fees for the conduct of all research, preclinical development and IND-enabling activities performed by us under the Janssen Agreement.

We determined the common stock purchase by JJDC represented a premium of $9.93 per share, or $16.0 million in aggregate (the Equity Premium), and the remaining $34.0 million was recorded as issuance of common stock in shareholders' equity.

We concluded that Janssen represented a customer, and in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606), we determined that the initial transaction price under the Janssen Agreement equals $66.0 million, consisting of the upfront, non-refundable and non-creditable payment of $50.0 million and the Equity Premium of $16.0 million. In addition, we identified our potential performance obligations under the Janssen Agreement, including our grant to Janssen of a license to certain of our intellectual property subject to certain conditions, our conduct of research and development services, and our participation in various joint oversight committees. We determined that our grant of a license to Janssen and our conduct of research and development services should be accounted for as one combined performance obligation, and that the combined performance obligation is transferred over the expected term of the conduct of the research and development services, which is estimated to be four years. Additionally, we determined that participation in the various joint oversight committees did not constitute a performance obligation as our participation in the various joint oversight committees does not transfer a service.

During the year ended December 31, 2021, we achieved a pre-defined research milestone under the Janssen Agreement and received a cash payment of $3.0 million.

During the year ended December 31, 2021, we recognized $43.7 million of collaboration revenue under the Janssen Agreement. During the year ended December 31, 2020, we recognized $16.8 million of collaboration revenue under the Janssen Agreement. As of December 31, 2021, aggregate deferred revenue related to the Janssen Agreement was $48.3 million.

Agreement with Ono Pharmaceutical Co., Ltd.

On September 14, 2018, we entered into a Collaboration and Option Agreement (the Ono Agreement) with Ono for the joint development and commercialization of two off-the-shelf iPSC-derived CAR T-cell product candidates (Candidate 1 and Candidate 2). Pursuant to the terms of the Ono Agreement, we received an upfront, non-refundable and non-creditable payment of $10.0 million. Additionally, we are entitled to receive fees for the conduct of research and development under a joint development plan, which fees are estimated to be $20.0 million in aggregate.

We concluded that Ono represented a customer and in accordance with ASC 606, we determined that the initial transaction price under the Ono Agreement equals $30.0 million, consisting of the upfront, non-refundable and non-creditable payment of $10.0 million and the aggregate estimated research and development fees of $20.0 million. In addition, we identified our performance obligations under the Ono Agreement, including our grant to Ono of a license to certain of our intellectual property subject to certain conditions, our conduct of research services, and our participation in a joint steering committee. We determined that all performance obligations should be accounted for as one combined performance obligation since no individual performance obligation is distinct, and that the combined performance obligation is transferred over the expected term of the conduct of the research services, which is estimated to be four years.

On December 4, 2020, we entered into a letter agreement (the Ono Letter Agreement) with Ono in connection with the Ono Agreement. Pursuant to the Ono Letter Agreement, Ono delivered to us proprietary antigen binding domains targeting an antigen expressed on certain solid tumors and nominated such antigen binding domains as the Ono Antigen Binding Domain for incorporation into Candidate 2. In connection with such nomination, Ono paid us a milestone fee of $10.0 million for further research and development of Candidate 2 under the Ono Agreement, and Ono continues to maintain its option to Candidate 2 under the Ono Agreement.

In addition, together with Ono, we agreed to the termination of the Ono Agreement with respect to Candidate 1. We retain all rights, in our sole discretion, to research, develop and commercialize Candidate 1 throughout the world without any obligation to Ono.

During the years ended December 31, 2021 and 2020, we recognized $12.1 million and $14.6 million, respectively, of collaboration revenue under the Ono Agreement. As of December 31, 2021, aggregate deferred revenue related to the Ono Agreement and Ono Letter Agreement was $0.3 million.

Research and Development Expenses

Research and development expenses consist of costs associated with the research, preclinical development, process and scale-up development, manufacture and clinical development of our product candidates, the research and development of our cell programming technology including our iPSC product platform, and the performance of research and development activities under our collaboration agreements. These costs are expensed as incurred and include:

- salaries and employee-related costs, including stock-based compensation;
- costs incurred under clinical trial agreements with investigative sites;

- costs to acquire, develop and manufacture preclinical study and clinical trial materials, including our product candidates;
- costs associated with conducting our preclinical, process and scale-up development, manufacturing, clinical and regulatory activities, including fees paid to third-party professional consultants, service providers and suppliers;
- costs incurred for our research, development and manufacturing activities, including under our collaboration agreements;
- costs for laboratory equipment, materials and supplies for the manufacture of our product candidates and the conduct of our research activities;
- costs incurred to license and maintain intellectual property; and
- facilities, depreciation and other expenses including allocated expenses for rent and maintenance of facilities.

We plan to increase our current level of research and development expenses for the foreseeable future as we continue the clinical and preclinical development of our product candidates, research and develop our cell programming technology including our iPSC product platform, and perform our obligations under collaboration agreements including under our agreements with Janssen and Ono. Our current planned research and development activities over the next twelve months consist primarily of the following:

- conducting clinical trials of our product candidates, including through the engagement of CROs to manage various aspects of our clinical trials;
- conducting GMP production, process and scale-up development and technology transfer activities for the manufacture of our product candidates, including those undergoing clinical investigation and IND-enabling preclinical development;
- procuring laboratory equipment, materials and supplies for the manufacture of our product candidates and the conduct of our research activities;
- conducting preclinical and clinical research to investigate the therapeutic activity of our product candidates; and
- conducting research, development and manufacturing activities, including under our sponsored research and collaboration agreements with Janssen and Ono.

Due to the inherently unpredictable nature of preclinical and clinical development and manufacture, and given our novel therapeutic approach and the current stage of development of our product candidates, we cannot determine and are unable to estimate with certainty the timelines we will require and the costs we will incur for the development and manufacture of our product candidates. Clinical and preclinical development and manufacturing timelines and costs, and the potential of development and manufacturing success, can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development and manufacturing plans and capital requirements. We cannot predict the effects of the impact of the ongoing COVID-19 pandemic on our business and operations, and our expenditures may be increased by delays or disruptions due to the COVID-19 pandemic, including as a result of actions we take in the near term to ensure business continuity and protect against possible supply chain shortages.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for our employees in executive, operational, finance and human resource functions; professional fees for accounting, legal and tax services; costs for obtaining, prosecuting and maintaining our intellectual property; and other costs and fees, including director and officer insurance premiums, to support our operations as a public company. We anticipate that our general and administrative expenses will increase in the future as we increase our research and development activities, maintain compliance with exchange listing and SEC requirements and continue to operate as a public company.

Other Income (Expense)

Other income (expense) consists of changes in the fair value of stock price appreciation milestones associated with the Amended and Restated Exclusive License Agreement dated May 15, 2018 (the Amended MSK License) with Memorial Sloan Kettering Cancer Center (MSK), interest income earned on cash and cash equivalents and interest income from investments (including the amortization of discounts and premiums).

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to the fair value of the stock price appreciation milestones for the Amended MSK License, accrued expenses, stock-based compensation, and the estimated total costs expected to be incurred under our collaboration agreement. We base our estimates on historical experience, known trends and events, financial models, and various other factors that are believed to be reasonable under the circumstances, the results of which 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 these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Annual Report, we believe that the following critical accounting policies reflect the more significant procedures, estimates and assumptions used in the preparation of our consolidated financial statements.

Revenue Recognition

We recognize revenue in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration we are entitled to receive in exchange for such product or service. In doing so, we follow a five-step approach: (i) identify the contract 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, and (v) recognize revenue when (or as) the customer obtains control of the product or service. We consider the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard. We apply the revenue recognition standard, including the use of any practical expedients, consistently to contracts with similar characteristics and in similar circumstances.

A customer is a party that has entered into a contract with us, where the purpose of the contract is to obtain a product or a service that is an output of our ordinary activities in exchange for consideration. To be considered a contract, (i) the contract must be approved (in writing, orally, or in accordance with other customary business practices), (ii) each party's rights regarding the product or the service to be transferred can be identified, (iii) the payment terms for the product or the service to be transferred can be identified, (iv) the contract must have commercial substance (that is, the risk, timing or amount of future cash flows is expected to change as a result of the contract), and (v) it is probable that we will collect substantially all of the consideration to which we are entitled to receive in exchange for the transfer of the product or the service.

A performance obligation is defined as a promise to transfer a product or a service to a customer. We identify each promise to transfer a product or a service (or a bundle of products or services, or a series of products and services that are substantially the same and have the same pattern of transfer) that is distinct. A product or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) our promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not separately identifiable from other promises in the contract, such promises should be combined into a single performance obligation.

The transaction price is the amount of consideration we are entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, we consider the existence of any significant financing component, the effects of any variable elements, noncash considerations and consideration payable to the customer. If a significant financing component exists, the transaction price is adjusted for the time value of money. If an element of variability exists, we must estimate the consideration we expect to receive and use that amount as the basis for recognizing revenue as the product or the service is transferred to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts.

If a contract has multiple performance obligations, we allocate the transaction price to each distinct performance obligation in an amount that reflects the consideration we are entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) we transfer control of the product or the service applicable to such performance obligation.

In those instances where we first receive consideration in advance of satisfying its performance obligation, we classify such consideration as deferred revenue until (or as) we satisfy such performance obligation. In those instances where we first satisfy our performance obligation prior to our receipt of consideration, the consideration is recorded as accounts receivable.

We expense incremental costs of obtaining and fulfilling a contract as and when incurred if the expected amortization period of the asset that would be recognized is one year or less, or if the amount of the asset is immaterial. Otherwise, such costs are capitalized as contract assets if they are incremental to the contract and amortized to expense proportionate to revenue recognition of the underlying contract.

Stock Price Appreciation Milestones

We estimate the fair value of the stock price appreciation milestones under the Amended MSK License using a Monte Carlo simulation model, which relies on our current stock price at the end of each quarter as well as significant estimates and assumptions to determine the estimated liability associated with the contingent milestone payments. We account for the fair value of the stock price appreciation milestones in accordance with ASC 815, *Derivatives and Hedging*, with fair value marked to market. The assumptions used to calculate the fair value of the stock price appreciation milestones are subject to a significant amount of judgment including the assessment of achieving a specified clinical milestone, the expected volatility of our common stock, the risk-free interest rate and the estimated term, which is based in part on the last valid patent claim date. We achieved the specified clinical milestone in July 2021 and met the first milestone during fiscal 2021. Accordingly, we remitted a payment to MSK of $20.0 million in the year ended December 31, 2021. We remeasure the fair value of the remaining stock price appreciation milestones at each balance sheet date, with changes in fair value recorded in earnings as a non-operating income or expense.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of accrued research and development expenses include amounts owed to clinical research organizations, to investigative sites in connection with clinical trials, to sponsored research organizations, to service providers in connection with preclinical development activities and to service providers related to product manufacturing, development and distribution of clinical supplies.

We base our accrued expenses related to clinical trials on our estimates of the services performed and efforts expended pursuant to our contractual arrangements, including those with clinical research organizations. The financial terms of these agreements are sometimes subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our service providers will exceed the level of services performed and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly.

Although we do not expect our estimates to be materially different from expenses actually incurred, if our estimates of the status and timing of services performed differs from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. To date, there have been no material differences from our estimates to the amounts actually incurred.

Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of employee stock option and restricted stock unit grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. Performance-based stock units/awards represent a right to receive a certain number of shares of common stock based on the achievement of corporate performance goals and continued employment during the vesting period. During the year ended December 31, 2021, we granted 1,997,377 performance-based restricted stock units with a total grant date fair value of approximately $121.9 million. At each reporting period, and to the extent achievement of one or any of the performance conditions is probable, we reassess the probability of the achievement of such corporate performance goals and any increase or decrease in share-based compensation expense resulting from an adjustment in the estimated shares to be released is treated as a cumulative catch-up in the period of adjustment.

We estimate the fair value of stock option grants using the Black-Scholes option pricing model, with the exception of option grants with both performance-based milestones and market conditions, which are valued using a lattice-based model. These models require the use of highly subjective and complex assumptions which determine the fair value of stock-based awards, (a) the risk-free interest rate, (b) the expected volatility of our stock, (c) the expected term of the award and (d) the expected dividend yield. The expected volatility is based on the historical volatility of our common stock over the most recent period commensurate with the estimated expected term of our stock options which is derived from historical experience and anticipated future exercise behavior. The risk-free interest rates for periods within the expected life of the option are based on the yields of zero-coupon U.S. Treasury securities. See Note 9 of the notes to the consolidated financial statements for additional information.

The fair value of our restricted stock units, including performance-based restricted stock units, is based on the closing price of our common stock as reported on The NASDAQ Global Market on the date of grant.

Recent Accounting Pronouncements

For a discussion of recently issued accounting pronouncements, please see Note 1 of the notes to the consolidated financial statements.

Results of Operations

Comparison of Years Ended December 31, 2021 and 2020

The following table summarizes the results of our operations for the years ended December 31, 2021 and 2020:

	Years Ended December 31,		Increase/ (Decrease)
	2021	2020	
	(in thousands)		
Collaboration revenue	$ 55,846	$ 31,434	$ 24,412
Research and development expenses	215,519	125,623	89,896
General and administrative expenses	57,321	33,896	23,425
Total other income (expense), net	4,843	(45,302)	50,145

Revenue. During the year ended December 31, 2021, we recognized revenue of $55.8 million, under our collaboration agreements with Janssen and Ono. During the year ended December 31, 2020, we recognized revenue of $31.4 million under our collaboration agreements with Janssen and Ono.

Research and development expenses. Research and development expenses were $215.5 million for the year ended December 31, 2021, compared to $125.6 million for the year ended December 31, 2020. The increase in research and development expenses was attributable primarily to the following:

- $40.9 million increase in employee compensation and benefits expense, which includes a $16.5 million increase in employee-stock based compensation expense;
- $24.0 million increase in expenditures for laboratory materials and supplies relating to the manufacture of our product candidates and the conduct of our research activities, including under our collaboration agreements; and
- $19.4 million increase in third-party professional consultant and clinical trial related expense.

General and administrative expenses. General and administrative expenses were $57.3 million for the year ended December 31, 2021, compared to $33.9 million for the year ended December 31, 2020. The increase in general and administrative expenses was attributable primarily to the following:

- $13.4 million increase in employee compensation and benefits expense, which includes a $7.1 million increase in employee stock-based compensation expense;
- $2.9 million increase in office and computer supplies, including software licenses;
- $2.5 million increase in facility lease and related expenses primarily relating to our new headquarters lease; and
- $1.0 million increase in insurance related expenses.

Other income (expense), net. Other income (expense), net was $4.8 million and ($45.3) million for the years ended December 31, 2021 and 2020, respectively. During the year ended December 31, 2021, we recorded $3.5 million in other income attributable to the fair value of the stock price appreciation milestone under the Amended MSK License. Other income (expense), net

for the year ended December 31, 2021 also consisted of interest income earned on cash and cash equivalents and interest income from investments (including the amortization of discounts and premiums). During the year ended December 31, 2020, we recorded $47.7 million in other expense attributable to the fair value of the stock price appreciation milestones under the Amended MSK License. Other income (expense), net for the year ended December 31, 2020 also consisted of interest income earned on cash and cash equivalents and interest income from investments (including the amortization of discounts and premiums).

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since inception. As of December 31, 2021, we had an accumulated deficit of $769.1 million and anticipate that we will continue to incur net losses for the foreseeable future.

The following table sets forth a summary of the net cash flow activity for each of the years ended December 31:

	2021	2020
	(in thousands)	
Net cash used in operating activities	$ (162,870)	$ (39,229)
Net cash used in investing activities	(324,023)	(161,076)
Net cash provided by financing activities	453,129	282,838
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (33,764)	$ 82,533

Operating Activities

Cash used in operating activities increased from $39.2 million for the year ended December 31, 2020 to $162.9 million for the year ended December 31, 2021. The primary drivers of this change in cash used in operating activities was our increase of $38.8 million in net loss and the one-time receipt of the $50.0 million upfront payment from Janssen in connection with entering into the Janssen Agreement in April 2020, which was not repeated in 2021. Additionally, during the year ended December 31, 2021, we achieved the first milestone under the Amended MSK License, and as a result paid $20.0 million to MSK.

Agreement with Janssen Biotech, Inc.

On April 2, 2020 (the Janssen Agreement Effective Date), we entered into the Janssen Agreement with Janssen to develop iPSC-derived CAR NK- and CAR T-cell product candidates for the treatment of cancer. Additionally, on the Janssen Agreement Effective Date, we entered into the Stock Purchase Agreement with JJDC. Under the terms of the Janssen Agreement and the Stock Purchase Agreement taken together, we received $100.0 million as of the Janssen Agreement Effective Date, of which $50.0 million was an upfront cash payment and $50.0 million was in the form of an equity investment by JJDC. Of the $50.0 million equity investment, $16.0 million represented a premium over the fair value of our common stock and was classified under operating activities.

We are entitled to receive fees for the conduct of all research, preclinical development and IND-enabling activities performed by us under the Janssen Agreement. Additionally, we are eligible to receive (i) with respect to the first Janssen Cancer Target, payments of up to $898.0 million upon the achievement of specified development, regulatory and sales milestones (the Janssen Milestone Payments) for the first Collaboration Candidate, and up to $460.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the first Janssen Cancer Target; and (ii) with respect to each of the second, third and fourth Janssen Cancer Targets, payments of up to $706.0 million in Janssen Milestone Payments for each of the first Collaboration Candidates, and up to $340.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the applicable Janssen Cancer Target, where certain Janssen Milestone Payments are subject to reduction in the event we elect to co-commercialize and share equally in the profits and losses in the United States of a respective Collaboration Candidate. We are further eligible to receive double-digit tiered royalties ranging up to the mid-teens on net sales of Collaboration Candidates that are commercialized by Janssen under the Janssen Agreement, subject to reduction under certain circumstances.

During the year ended December 31, 2021, we achieved a pre-defined research milestone under the Janssen Agreement and received a cash payment of $3.0 million. As of December 31, 2021, no royalties have been paid to us.

In connection with the Janssen Agreement, we have incurred $13.6 million in sublicense fees to certain of our existing licensors, of which $13.3 million has been paid as of December 31, 2021. The $13.6 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs.*

Agreement with Ono Pharmaceutical Co., Ltd.

On September 14, 2018, we entered into the Ono Agreement with Ono for the joint development and commercialization of two off-the-shelf, iPSC-derived CAR T-cell product candidates (each a Candidate and collectively the Candidates). Under the terms of the Ono Agreement, Ono paid to us an upfront, non-refundable and non-creditable payment of $10.0 million. Additionally, as consideration for our conduct of research and preclinical development under a joint development plan, Ono pays us annual research and development fees set forth in the annual budget included in the joint development plan, which fees are estimated to be $20.0 million in aggregate over the course of the joint development plan. Further, under the terms of the Ono Agreement, Ono had agreed to pay us up to an additional $40.0 million, subject to the achievement of a preclinical milestone and the exercise by Ono of its options to obtain exclusive licenses to develop and commercialize the Candidates. Such fees are in addition to the upfront payment and research and development fees.

Pursuant to the Ono Agreement, we and Ono are jointly conducting research and development activities under a joint development plan, with the goal of advancing Candidate 2 to a pre-defined preclinical milestone. We have granted to Ono, during a specified period of time, an option to obtain an exclusive license under certain intellectual property rights to develop and commercialize Candidate 2 in all territories of the world, with us retaining the right to co-develop and co-commercialize Candidate 2 in the United States and Europe under a joint arrangement whereby it is eligible to share at least 50% of the profits and losses.

On December 4, 2020, we entered into the Ono Letter Agreement with Ono in connection with the Ono Agreement. Pursuant to the Ono Letter Agreement, Ono delivered to us proprietary antigen binding domains targeting an antigen expressed on certain solid tumors and nominated such antigen binding domains as the Ono Antigen Binding Domain for incorporation into Candidate 2. In connection with such nomination, Ono paid us a milestone fee of $10.0 million in December 2020 for further research and development of Candidate 2 under the Ono Agreement, and Ono continues to maintain its option to Candidate 2 under the Ono Agreement. In addition, the Ono Letter Agreement terminated further development with respect to Candidate 1.

Subject to Ono's exercise of its options to obtain exclusive licenses to develop and commercialize Candidate 2 and to the achievement of certain clinical, regulatory and commercial milestones in specified territories, we are eligible to receive an aggregate of up to $885.0 million in milestone payments for Candidate 2, with the applicable milestone payments for Candidate 2 for the United States and Europe subject to reduction by 50% if we elect to co-develop and co-commercialize Candidate 2 as described above. As of December 31, 2021, we have not received any milestone payments other than the $10.0 million associated with the Ono Letter Agreement in December 2020. We are also eligible to receive tiered royalties ranging from the mid-single digits to the low-double digits based on annual net sales by Ono for Candidate 2 in specified territories, with such royalties subject to certain reductions. As of December 31, 2021, no royalties have been paid to us.

As a direct result of our entry into the Ono Agreement and the Ono Letter Agreement, we incurred an aggregate of $4.0 million in sublicense consideration to certain of our existing licensors. The $4.0 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs.* As of December 31, 2021, all such consideration has been paid, with $2.0 million paid during the year ending December 31, 2021.

Memorial Sloan Kettering Cancer Center License Agreement

On May 15, 2018, we entered into the Amended MSK License with MSK. The Amended MSK License amends and restates the Exclusive License Agreement entered into between us and MSK on August 19, 2016, pursuant to which we entered into an exclusive license agreement with MSK for rights relating to compositions and methods covering iPSC-derived cellular immunotherapy, including T-cells and NK-cells derived from iPSCs engineered with CARs.

Pursuant to the Amended MSK License, MSK granted us additional licenses to certain patents and patent applications relating to new CAR constructs and off-the-shelf CAR T cells, including the use of clustered regularly interspaced short palindromic repeat (CRISPR) and other innovative technologies for their production, in each case to research, develop, and commercialize licensed products in the field of all human therapeutic uses worldwide. We have the right to grant sublicenses to certain licensed rights in accordance with the terms of the Amended MSK License, in which case we are obligated to pay MSK a percentage of certain sublicense income received.

In the event a licensed product achieves a specified clinical milestone, MSK is then eligible to receive certain milestone payments totaling up to $75.0 million based on the price of our common stock, where the amount of such payments owed to MSK is contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone. These payments are based on common stock price multiples, with the numerator being the fair value of the ten-trading day trailing average closing price of our common stock and the denominator being the ten-trading day trailing average closing price of our common stock as of the effective date of the Amended MSK License, adjusted for any stock splits, cash dividends, stock dividends, other distributions, combinations, recapitalizations, or similar events. Under the terms of the Amended MSK License, upon a change of control of our company, in certain circumstances, we may be required to pay a portion of these payments to MSK based on the price of our common stock in connection with such change of control.

As of December 31, 2021, we recorded a liability of $24.2 million associated with the remaining stock price appreciation milestones for the Amended MSK License. In July 2021, we achieved a specified clinical milestone for a licensed product under the Amended MSK License and our ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. As a result, we remitted the first milestone payment of $20.0 million to MSK.

Investing Activities

During the years ended December 31, 2021 and 2020, investing activities used cash of $324.0 million and $161.1 million, respectively. During the year ended December 31, 2021 we purchased $968.2 million of investments, which were partially offset by $694.8 million in maturities of investments. During the year ended December 31, 2020, we purchased $277.3 million of investments, offset by $121.2 million in maturities of investments. The remaining investing activities for the periods presented were primarily attributable to the purchase of property and equipment.

Financing Activities

Financing activities provided cash of $453.1 million for the year ended December 31, 2021, which primarily consisted of $432.4 million of net proceeds from our January 2021 public offering of common stock and issuance of pre-funded warrants and $20.7 million received from the issuance of common stock from equity incentive plans pursuant to the exercise of employee stock options.

Financing activities provided cash of $282.8 million for the year ended December 31, 2020, which primarily consisted of $188.8 million of net proceeds from our June 2020 public offering of common stock, $50.0 million of net proceeds from our June 2020 private placement of common stock, and $33.9 million of net proceeds from the issuance of common stock in conjunction with our collaboration agreement with Janssen, which amount represents the fair value of the equity component from Janssen's common stock purchase in connection with the collaboration agreement.

From our inception through December 31, 2021 we have funded our consolidated operations primarily through the public and private sale of common stock, the private placement of preferred stock and convertible notes, commercial bank debt and revenues from collaboration activities and grants. As of December 31, 2021, we had aggregate cash and cash equivalents and investments of $716.6 million.

Private Placement of Common Stock

In June 2020, in connection with the June 2020 public offering of common stock, the Company exercised its right to cause an existing shareholder, Johnson & Johnson Innovation-JJDC, Inc (JJDC) to purchase $50.0 million of the Company's common stock, and JJDC purchase in a private placement 1.8 million shares of the Company's common stock at a price of $28.31 per share, for aggregate proceeds of $50.0 million. In April 2020, we entered into a Stock Purchase Agreement with JJDC. Under the Stock Purchase Agreement, we sold 1.6 million shares of our common stock to JJDC at $31.00 per share, for an aggregate purchase price of $50.0 million. The shares of common stock purchased as part of these private placements were not subject to underwriting discounts or commissions.

Public Offerings of Common Stock

In June 2020, we completed a public offering of common stock in which investors, certain of which are affiliated with one of our directors, purchased 7.1 million shares of our common stock at a price of $28.31 per share under a shelf registration statement. Gross proceeds from the offering were $201.3 million. After giving effect to $12.5 million in underwriting discounts, commissions and expenses related to the offering, net proceeds were $188.8 million.

In January 2021, we completed a public offering of common stock in which investors, certain of which are affiliated with a director of ours, purchased 5.1 million shares of our common stock at a price of $85.50 per share under a shelf registration statement. In addition, we issued pre-funded warrants, in lieu of common stock to certain investors, to purchase 257,310 shares of our common stock (Pre-Funded Warrants). The purchase price of for the Pre-Funded Warrants was $85.499 per Pre-Funded Warrant, which equals the per share public offering price for the shares of common stock less the $0.001 exercise price for each such Pre-Funded Warrant. See Note 8 for additional detail. Gross proceeds from the public offering and the issuance of the Pre-Funded Warrants were $460.0 million. After giving effect to $27.6 million in underwriting discounts, commissions and expenses related to the public offering and the issuance of Pre-Funded Warrants, net proceeds were $432.4 million.

California Institute for Regenerative Medicine Award

On April 5, 2018, we executed an award agreement with the CIRM pursuant to which CIRM awarded us $4.0 million to advance our FT516 product candidate into a first-in-human clinical trial (the Award). Pursuant to the terms of the Award, we are

eligible to receive five disbursements in varying amounts totaling $4.0 million throughout the project period of the Award. In November 2019, we submitted an IND application for FT516 in advanced solid tumors. As of December 31, 2021, we have received aggregate disbursements under the Award in the amount of $4.0 million.

The Award is subject to certain co-funding requirements by us. We, in our sole discretion, have the option to treat the Award either as a loan or as a grant. In the event we elect to treat the Award as a loan, we will be obligated to repay i) 60%, ii) 80%, iii) 100% or iv) 100% plus interest at 7% plus LIBOR, of the total Award to CIRM, where such repayment rate is dependent upon the phase of clinical development of FT516 at the time of our election. If we do not elect to treat the Award as a loan within 10 years of the date of the Award, the Award will be considered a grant and we will be obligated to pay to CIRM a royalty on commercial sales of FT516 until such royalty payments equal nine times the total amount awarded to us under the Award.

Registration Statements on Form S-3

In November 2021, we filed an automatic shelf registration statement (File No. 333-260772), which became effective upon filing. The shelf registration statement allows us to issue certain securities, including shares of our common stock, from time to time. The specific terms of any offering under the automatic shelf registration statement are established at the time of such offering. Additionally, we entered into a sales agreement with Jefferies Group LLC (Jefferies) with respect to an at-the-market offering program, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $350.0 million through Jefferies as the sales agent, pursuant to this automatic shelf registration statement.

Operating Capital Requirements

We anticipate that we will continue to incur losses for the foreseeable future, and we expect the losses to increase as we continue the research, manufacture and development of, and seek regulatory approvals for, our product candidates and conduct additional research, manufacturing and development activities pursuant to our collaboration agreements with Janssen and Ono. Our product candidates have not yet achieved regulatory approval and we may not be successful in achieving commercialization of our product candidates.

We believe our existing cash and cash equivalents and investments as of December 31, 2021 will be sufficient to fund our projected operating requirements for at least the next twelve months. However, we are subject to all the risks and uncertainties incident in the research, manufacture and development of therapeutic products. For example, the FDA or other regulatory authorities may require us to generate additional data or conduct additional preclinical studies, manufacturing activities, or clinical trials, or may impose other requirements beyond those that we currently anticipate. Additionally, it is possible for a product candidate to show promising results in preclinical studies or in clinical trials, but fail to establish sufficient safety and efficacy data necessary to obtain regulatory approvals. As a result of these and other risks and uncertainties and the probability of success, the duration and the cost of our research, manufacturing and development activities required to advance a product candidate cannot be accurately estimated and are subject to considerable variation. We may encounter difficulties, complications, delays and other unknown factors and unforeseen expenses in the course of our research, manufacturing and development activities, any of which may significantly increase our capital requirements and could adversely affect our liquidity.

We will require additional capital for the research, manufacture and development of our product candidates and to perform our obligations under our collaboration agreements, and we may need to seek additional funds sooner than expected due to any changes in our business, operations, financial condition or prospects, including any impacts of the COVID-19 pandemic. We expect to finance our capital requirements in the foreseeable future through the sale of public or private equity or debt securities. However, additional capital may not be available to us on reasonable terms, if at all. 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 research, manufacture or development of one or more of our product candidates. If we do raise additional funds through the issuance of additional equity or debt securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. Additionally, if we incur indebtedness, we may become subject to financial or other covenants that could adversely restrict, impair or affect our ability to conduct our business, such as requiring us to relinquish rights to certain of our product candidates or technologies or limiting our ability to acquire, sell or license intellectual property rights or incur additional debt. Any of these events could significantly harm our business, operations, financial condition and prospects. In addition, while the full impact of the COVID-19 pandemic on our business, operations, financial condition and prospects, and on the global economy, are currently unknown and difficult to predict, the pandemic has caused significant disruptions and created uncertainties in the global financial markets, and the economic impacts of the pandemic could materially and adversely affect our ability to raise capital through equity or debt financings in the future.

Our forecast of the period of time through which our existing cash and cash equivalents and investments will be adequate to support our operations is a forward-looking statement and involves significant risks and uncertainties. We have based this forecast on assumptions that may prove to be wrong, and actual results could vary materially from our expectations, which may adversely affect our capital resources and liquidity. We could utilize our available capital resources sooner than we currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the initiation, timing, progress, size, duration, costs and results of our clinical trials and preclinical studies for our product candidates;
- the number and the nature of product candidates and indications that we pursue;
- the time to and cost of establishing business operations at our new corporate headquarters, including internal GMP production capabilities to support the clinical and potential commercial manufacture of our product candidates;
- the cost of GMP production, process and scale-up development and technology transfer activities for the manufacture of our product candidates, including the cost of laboratory equipment, materials and supplies to support these activities;
- the time, cost and outcome of seeking and obtaining regulatory approvals;
- the extent to which we are required to pay milestone or other payments under our existing in-license agreements and any in-license agreements that we may enter into in the future, and the timing of such payments, including payments owed to MSK in connection with the stock price appreciation milestones;
- the extent to which milestones are achieved under our collaboration agreements with Ono and Janssen, and any other strategic partnership or collaboration agreements that we may enter into in the future, and the time to achievement of such milestones and our receipt of any associated milestone payments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the cost of our research and development activities, including our need and ability to hire additional employees and procure additional equipment, materials and supplies;
- the establishment and continuation of collaborations and strategic alliances;
- the timing and terms of future in-licensing and out-licensing transactions; and
- the cost of establishing sales, marketing, manufacturing and distribution capabilities for, and the pricing and reimbursement of, any products for which we may receive regulatory approval.

In addition, we are closely monitoring ongoing developments in connection with the COVID-19 pandemic and evaluating adjustments to our business and operations, which may negatively impact our financial condition and prospects and our operating results. We will continue to assess our operating capital requirements and may make adjustments to our business and operations if circumstances warrant. If we cannot continue or expand our research, manufacturing and development operations, or otherwise capitalize on our business opportunities, because we lack sufficient capital, our business, operations, financial condition and prospects could be materially adversely affected**.**

Contractual Obligations and Commitments

We lease our headquarters office and laboratory space under a non-cancelable operating lease, comprising approximately 200,000 square feet. In addition to rent, the lease is subject to certain fixed amenities fees. Lease payments commenced in May 2021 (the Rent Commencement Date) and the lease has a lease term of 15 years starting from the Rent Commencement Date. We have the option to extend the lease for two successive five-year periods. We also have a one-time option to terminate the lease after 10 years from the Rent Commencement Date, subject to payment of a $30.0 million early termination fee. See Note 8 of the consolidated financial statements for additional detail.

Total undiscounted aggregate future operating lease obligations under all of our operating leases as of December 31, 2021 are $192.6 million.

We have no material contractual obligations not fully recorded on our consolidated balance sheets or fully disclosed in the notes to the financial statements.

We have obligations under various license agreements to make future payments to third parties that become due and payable on the achievement of certain development, regulatory and commercial milestones (such as the start of a clinical trial, filing for product approval with the FDA or other regulatory agencies, product approval by the FDA or other regulatory agencies, product launch or product sales) or on the sublicense of our rights to another party. We have not included these commitments on our balance sheet

because the achievement and timing of these events is not fixed and determinable. Certain milestones are in advance of receipt of revenue from the sale of products and, therefore, we may require additional debt or equity capital to make such payments. These commitments include:

- Under a license agreement with the Whitehead Institute for Biomedical Research, pursuant to which we license certain patents relating to our iPSC product platform, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $2.3 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of any sublicense income.
- Under license agreements with The Scripps Research Institute (TSRI), pursuant to which we license certain patents relating to our iPSC product platform, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make are $1.8 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low- to mid-single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under these agreements, and we will be required to pay a percentage of any sublicense income.
- Under a license agreement with the Regents of the University of Minnesota, pursuant to which we license certain patents relating to compositions and uses of NK cells and to compositions of engineered receptors and immune cells expressing such receptors, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $4.6 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of any sublicense income.
- Under a license agreement with Memorial Sloan Kettering Cancer Center, pursuant to which we license certain patents relating to compositions and uses of T cells derived from iPSCs, CARs and genetic modifications using CRISPR, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $12.5 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property up to the high-single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low- to mid-single digits. We have the right to sublicense our rights under this agreement, and we will be required to pay a percentage of any sublicense income. Additionally, in the event a licensed product achieves a specified clinical milestone, Memorial Sloan Kettering Cancer Center is then eligible to receive additional milestone payments, where the amount of such payments owed to Memorial Sloan Kettering Cancer Center are contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone. See Note 2 of the notes to the consolidated financial statements for additional detail related to the stock price appreciation milestone payments.
- Under a license agreement with Dana Farber Cancer Institute, pursuant to which we license certain patent applications relating to novel antibody fragments that bind the alpha-3 domain of MICA/B, we are required to make annual maintenance payments and payments based upon development, regulatory and commercial milestones for any products covered by the in-licensed intellectual property. The maximum aggregate milestone payments we may be obligated to make per product are $25 million. We will also be required to pay a royalty on net sales of products covered by the in-licensed intellectual property in the low single digits. The royalty is subject to reduction for any third-party payments required to be made, with a minimum floor in the low single digits. We have the right to sublicense our rights under these agreements, and we will be required to pay a percentage of any sublicense income.

We enter into contracts in the normal course of business, including with clinical sites, CROs, and other professional service providers for the conduct of clinical trials, contract manufacturers for the production of our product candidates, contract research service providers for preclinical research studies, professional consultants for expert advice and vendors for the sourcing of clinical and laboratory supplies and materials. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments.

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We are exposed to market risk primarily related to changes in interest rates. As of December 31, 2021, our cash and cash equivalents consisted of cash and money market mutual funds, and our investments consisted of United States treasuries and corporate debt securities with maturities up to eighteen months from the date of acquisition. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the relatively short-term nature and low risk profile of the instruments in our portfolio, a 10% change in market interest rates would not have a material impact on our financial condition and/or results of operations.

Stock Price Sensitivity

We entered into a license agreement with MSK under which we obtained rights relating to compositions and methods covering iPSC-derived cellular immunotherapy, including T cells and NK cells derived from iPSCs engineered with CARs. MSK is eligible to receive certain milestone payments totaling up to $75.0 million in the event a licensed product achieves a specified clinical milestone, where the amount of such payments owed to MSK is contingent upon certain increases in the price of our common stock following the date of achievement of such clinical milestone. As of December 31, 2021, the estimated fair value of the stock price appreciation milestones was $24.2 million. In July 2021, we achieved a specified clinical milestone for a licensed product under the Amended MSK License and our ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. As a result, the Company remitted the first milestone payment of $20.0 million to MSK.

Changes in the price our common stock as of each balance sheet date may cause a relatively large change in the estimated fair value of the stock price appreciation milestones and the associated liability and resulting expense or gain. See Note 5 to our consolidated financial statements for a related sensitivity analysis.

ITEM 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Fate Therapeutics, Inc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Fate Therapeutics, Inc. as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control- Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 28, 2022, expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. 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 audits 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 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Revenue recognition – Revenue Recognized Over Time

Description of the Matter	As more fully described in Note 2 of the financial statements, the Company has concluded that the grant of intellectual property licenses and the delivery of related research and development services under certain of its existing collaboration agreements represent a combined performance obligation for which the Company recognizes collaboration revenues as the research services are transferred over time. Revenue is recognized over the estimated period of time to conduct the research services based on an appropriate measure of progress towards satisfaction of the identified performance obligation. Collaboration revenue is significant to our audit because the revenue recognition assessment process involves inherent uncertainty, uses subjective assumptions, and the amounts involved are material to the financial statements taken as a whole. The subjective assumptions relate to the estimated total costs expected to be incurred and the estimated total full-time employees (FTEs) expected to be utilized under each agreement.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls over the Company's revenue recognition review process including controls over management's review of the significant assumptions described above. For example, we tested controls over the development of the estimated costs and estimated full-time employees to complete and the review of the estimates by management. To test revenue recognized we performed audit procedures that included, among other things, testing the assumptions and underlying data used by the Company in its computations and testing the accuracy of the computations. We inspected evidence supporting actual FTEs utilized and the amount of actual costs incurred and assessed whether they were appropriate costs according to the terms of the contract. We performed corroborative inquiries of individuals outside of the finance department to assess the reasonableness of management's estimates of total estimated costs and total FTEs to understand the progress to date and the estimate of total inputs. In addition, we performed sensitivity analyses, including assessing the reasonableness of the estimated costs to be incurred and estimated FTEs to be utilized as of the reporting date based on current factors.

/s/ Ernst & Young, LLP

We have served as the Company's auditor since 2009.

San Diego, California

February 28, 2022

Fate Therapeutics, Inc.

Consolidated Balance Sheets

(In thousands, except par value and share data)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 133,583	$ 167,347
Accounts receivable	8,676	5,515
Short-term investments and related maturity receivables	482,327	315,569
Prepaid expenses and other current assets	8,826	5,892
Total current assets	633,412	494,323
Long-term investments	100,664	—
Property and equipment, net	91,529	32,308
Operating lease right-of-use assets	70,720	67,084
Restricted cash	15,227	15,227
Collaboration contract assets	9,870	13,506
Other assets	33	9
Total assets	$ 921,455	$ 622,457
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,612	$ 6,283
Accrued expenses	42,412	15,564
CIRM award liability, current portion	3,200	3,200
Deferred revenue, current portion	21,483	21,144
Operating lease liabilities, current portion	5,577	3,355
Stock price appreciation milestones, current portion	—	36,018
Total current liabilities	81,284	85,564
Deferred revenue, net of current portion	27,124	46,021
CIRM award liability, net of current portion	800	800
Operating lease liabilities, net of current portion	109,241	93,943
Stock price appreciation milestones, net of current portion	24,168	11,684
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; authorized shares—5,000,000 at December 31, 2021 and December 31, 2020; Class A Convertible Preferred shares issued and outstanding—2,794,549 at December 31, 2021 and December 31, 2020	3	3
Common stock, $0.001 par value; authorized shares—250,000,000 at December 31, 2021 and 150,000,000 at December 31, 2020; issued and outstanding—95,726,962 at December 31, 2021 and 87,722,237 at December 31, 2020	96	88
Additional paid-in capital	1,448,584	941,216
Accumulated other comprehensive (loss) gain	(762)	70
Accumulated deficit	(769,083)	(556,932)
Total stockholders' equity	678,838	384,445
Total liabilities and stockholders' equity	$ 921,455	$ 622,457

See accompanying notes.

Fate Therapeutics, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

	For the Years Ended December 31,		
	2021	2020	2019
Collaboration revenue	$ 55,846	$ 31,434	$ 10,680
Operating expenses:			
Research and development	215,519	125,623	87,770
General and administrative	57,321	33,896	23,637
Total operating expenses	272,840	159,519	111,407
Loss from operations	(216,994)	(128,085)	(100,727)
Other income (expense):			
Interest income	1,309	2,400	4,330
Interest expense	—	—	(1,752)
Change in fair value of stock price appreciation milestones	3,534	(47,702)	—
Total other income (expense), net	4,843	(45,302)	2,578
Net loss	$ (212,151)	$ (173,387)	$ (98,149)
Other comprehensive loss:			
Unrealized (loss) gain on available-for-sale securities, net	(832)	48	24
Comprehensive loss	$ (212,983)	$ (173,339)	$ (98,125)
Net loss per common share, basic and diluted	$ (2.24)	$ (2.10)	$ (1.44)
Weighted–average common shares used to compute basic and diluted net loss per share	94,747,311	82,385,319	68,190,741

See accompanying notes.

Fate Therapeutics, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity

(In thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	2,819,549	$ 3	64,693,681	$ 65	$ 445,799	$ (2)	$ (285,396)	$ 160,469
Exercise of stock options, net of issuance costs	—	—	787,434	1	2,595	—	—	2,596
Issuance of common stock upon vesting of restricted stock units	—	—	172,625	—	—	—	—	—
Stock–based compensation	—	—	—	—	17,410	—	—	17,410
Public offering of common stock, net of offering costs	—	—	9,890,000	10	162,396	—	—	162,406
Issuance of common stock upon cashless warrant exercise	—	—	61,520	—	—	—	—	—
Conversion of preferred shares to common stock	(25,000)	—	125,000	—	—	—	—	—
Unrealized gain on investments	—	—	—	—	—	24	—	24
Net loss	—	—	—	—	—	—	(98,149)	(98,149)
Balance at December 31, 2019	2,794,549	$ 3	75,730,260	$ 76	$ 628,200	$ 22	$ (383,545)	$ 244,756
Exercise of stock options, net of issuance costs	—	—	1,419,117	1	9,581	—	—	9,582
Issuance of common stock upon vesting of restricted stock units	—	—	85,000	—	—	—	—	—
Stock–based compensation	—	—	—	—	30,753	—	—	30,753
Public offering of common stock, net of offering costs	—	—	7,108,796	7	188,777	—	—	188,784
Private placement of common stock, net of issuance costs			1,766,160	2	49,973	—	—	49,975
Issuance of stock to collaboration partner, net of issuance costs	—	—	1,612,904	2	33,932	—	—	33,934
Unrealized gain on investments	—	—	—	—	—	48	—	48
Net loss	—	—	—	—	—	—	(173,387)	(173,387)
Balance at December 31, 2020	2,794,549	$ 3	87,722,237	$ 88	$ 941,216	$ 70	$ (556,932)	$ 384,445
Exercise of stock options, net of issuance costs	—	—	2,430,298	2	20,728	—	—	20,730
Issuance of common stock upon vesting of restricted stock units	—	—	451,620	1	—	—	—	1
Stock–based compensation	—	—	—	—	54,364	—	—	54,364
Public offering of common stock and issuance of pre-funded warrants, net of offering costs	—	—	5,122,807	5	432,276	—	—	432,281
Unrealized (loss) gain on investments, net	—	—	—	—	—	(832)	—	(832)
Net loss	—	—	—	—	—	—	(212,151)	(212,151)
Balance at December 31, 2021	2,794,549	$ 3	95,726,962	$ 96	$ 1,448,584	$ (762)	$ (769,083)	$ 678,838

See accompanying notes

Fate Therapeutics, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2021	**2020**	**2019**
Operating activities:			
Net loss	$ (212,151)	$ (173,387)	$ (98,149)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	5,850	3,087	2,193
Stock–based compensation	54,364	30,753	17,410
Amortization of debt discounts and debt issuance costs	—	—	115
Accretion and amortization of premiums and discounts on investments, net	5,067	1,676	(478)
Amortization of collaboration contract asset	3,995	3,110	620
Deferred revenue	(18,559)	60,603	(8,526)
Change in fair value of stock price appreciation milestones	(3,534)	47,702	—
Changes in assets and liabilities:			
Accounts receivable	(3,160)	(5,515)	500
Prepaid expenses and other assets	(3,052)	(13,582)	(1,911)
Accounts payable and accrued expenses	5,907	(1,554)	4,277
Right-of-use assets and lease liabilities, net	2,403	7,878	774
Net cash used in operating activities	(162,870)	(39,229)	(83,175)
Investing activities			
Purchases of property and equipment	(50,704)	(4,932)	(7,395)
Purchases of investments	(968,159)	(277,344)	(248,858)
Maturities of investments	694,840	121,200	98,800
Net cash used in investing activities	(324,023)	(161,076)	(157,453)
Financing activities			
Issuance of common stock from equity incentive plans, net of issuance costs	20,714	9,655	2,522
Proceeds from public offering of common stock, net of issuance costs	411,735	188,784	162,406
Proceeds from issuance of pre-funded warrants, net of issuance costs	20,680	—	—
Proceeds from private placement of common stock, net of issuance costs	—	49,975	—
Proceeds from sale of common stock to collaboration partner, net of issuance costs	—	33,934	—
Proceeds from CIRM award	—	490	—
Principal repayments of long–term debt	—	—	(15,000)
Net cash provided by financing activities	453,129	282,838	149,928
Net change in cash, cash equivalents and restricted cash	(33,764)	82,533	(90,700)
Cash, cash equivalents and restricted cash at beginning of the year	182,574	100,041	190,741
Cash, cash equivalents and restricted cash at end of the year	$ 148,810	$ 182,574	$ 100,041
Supplemental disclosure of cash flow information			
Interest paid	$ —	$ —	$ 2,291
Supplemental schedule of noncash investing and financing activities			
Purchases of property and equipment in accounts payable	$ 4,371	$ 1,486	$ 602
Right-of-use assets obtained in exchange for lease obligations	$ 8,600	$ 49,287	$ 13
Accrued issuance costs included in additional paid-in-capital	$ 133	$ —	$ —

See accompanying notes.

Fate Therapeutics, Inc.

Notes to Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

Organization

Fate Therapeutics, Inc. (the Company) was incorporated in the state of Delaware on April 27, 2007 and has its principal operations in San Diego, California. The Company is a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for patients with cancer, including off-the-shelf natural killer (NK) and T-cell product candidates derived from clonal master engineered induced pluripotent stem cell (iPSC) lines.

As of December 31, 2021, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure and has not generated any revenues from any sales of its therapeutic products. To date, the Company's revenues have been derived from collaboration agreements and government grants.

Public Equity Offerings

In January 2021, the Company completed a public offering of common stock in which investors, certain of which are affiliated with a director of the Company, purchased 5.1 million shares of the Company's common stock at a price of $85.50 per share under a shelf registration statement. In addition, the Company issued pre-funded warrants, in lieu of common stock to certain investors, to purchase 257,310 shares of the Company's common stock (Pre-Funded Warrants). The purchase price of the Pre-Funded Warrants was $85.499 per Pre-Funded Warrant, which equals the per share public offering price for the shares of common stock less the $0.001 exercise price for each such Pre-Funded Warrant. See Note 8 for additional detail. Gross proceeds from the public offering and the issuance of the Pre-Funded Warrants were $460.0 million, and after giving effect to $27.6 million of costs related to the public offering and the issuance of Pre-Funded Warrants, net proceeds were $432.4 million.

In June 2020, the Company completed a public offering of common stock in which investors, certain of which are affiliated with a director of the Company, purchased 7.1 million shares of its common stock at a price of $28.31 per share under a shelf registration statement. Gross proceeds from the offering were $201.3 million, and after giving effect to $12.5 million of costs related to the offering, net proceeds were $188.8 million.

In September 2019, the Company completed a public offering of common stock in which investors, certain of which are affiliated with a director of the Company, purchased 9.9 million shares of its common stock at a price of $17.50 per share under a shelf registration statement. Gross proceeds from the offering were $173.1 million, and, after giving effect to $10.7 million of costs related to the offering, net proceeds were $162.4 million.

Private Placements of Common Stock

In June 2020, in connection with the June 2020 public offering of common stock, the Company exercised its right to cause an existing shareholder, Johnson & Johnson Innovation-JJDC, Inc (JJDC), to purchase $50.0 million of the Company's common stock, and JJDC purchased in a private placement 1.8 million shares of the Company's common stock at a price of $28.31 per share, for aggregate proceeds of $50.0 million. In April 2020, in connection with the Janssen Agreement described in Note 2, JJDC purchased in a private placement 1.6 million shares of the Company's common stock at a price of $31.00 per share, for aggregate proceeds of $50.0 million. The shares of common stock purchased in the private placements were not subject to any underwriting discounts or commissions.

Use of Estimates

The Company's consolidated financial statements are prepared in accordance with United States generally accepted accounting principles (U.S. GAAP). The preparation of the Company's consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to its stock appreciation milestone obligations, contracts containing leases, accrued expenses and the estimated total costs expected to be incurred under the Company's collaboration agreements. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Risks and Uncertainties

Due to the global outbreak of SARS-CoV-2, the strain of coronavirus that causes Coronavirus disease 19 (COVID-19), including the emergence of new variants of the virus, the Company experienced impacts on certain aspects of its business, including its clinical trial and research and development activities, during the year ended December 31, 2021. For example, certain of the Company's research and development activities have been delayed or disrupted as a result of measures the Company implemented in response to governmental "stay at home" orders and in the interests of public health and safety, and the Company has experienced delays or disruptions in the initiation and conduct of its clinical trials as a result of prioritization of hospital and other medical resources toward pandemic efforts, policies and procedures implemented at clinical sites with respect to the conduct of clinical trials, and other precautionary measures taken in treating patients or in practicing medicine in response to the COVID-19 pandemic. The scope and duration of these delays and disruptions, and the ultimate impacts of COVID-19 on the Company's operations, are currently unknown. The Company is continuing to actively monitor the situation and may take further precautionary and preemptive actions as may be required by federal, state or local authorities or that it determines are in the best interests of public health and safety and that of the Company's patient community, employees, partners, and stockholders. The Company cannot predict the effects that such actions, or the impact of COVID-19 on global business operations and economic conditions, may have on its business, strategy, collaborations, or financial and operating results.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries, Fate Therapeutics Ltd., incorporated in the United Kingdom, Fate Therapeutics, B.V., incorporated in the Netherlands and Tfinity Therapeutics, Inc., incorporated in the United States. To date, the aggregate operations of these subsidiaries have not been significant and all intercompany transactions and balances have been eliminated in consolidation.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating and reportable segment.

Fair Value of Financial Instruments

The Company's financial instruments consist primarily of cash and cash equivalents, marketable securities, accounts receivable, stock price appreciation milestones, accounts payable, and accrued liabilities. The carrying amounts of accounts receivable, accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the relatively short-term nature of those instruments. Based on the borrowing rates available to the Company for loans with similar terms, which is considered a Level 2 as described below, the Company believes that the fair value of long-term debt approximates its carrying value during the periods when debt was outstanding.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three- tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents include cash in readily available checking and savings accounts, money market accounts and money market funds. The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amounts shown in the consolidated statements of cash flows as of December 31, 2021, 2020 and 2019 (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Cash and cash equivalents	$ 133,583	$ 167,347	$ 99,814
Restricted cash	15,227	15,227	227
Total cash, cash equivalents, and restricted cash shown in the consolidated statement of cash flows	$ 148,810	$ 182,574	$ 100,041

For the years ended December 31, 2021, 2020 and 2019, the restricted cash balance includes cash-collateralized irrevocable standby letters of credit in the amounts of $15.2 million, $15.2 million, and $0.2 million, respectively, associated with the Company's facilities leases.

Investments

Investments are accounted for as available-for-sale securities and are carried at fair value on the consolidated balance sheets. Upon initial recognition of the investment and at each reporting period, the Company evaluates whether any unrealized losses on investments are attributable to a credit loss or other factors. Any unrealized losses attributable to credit loss are recorded through an allowance for credit losses, limited to the amount by which the fair value is below amortized cost, with the offsetting amount recorded in other income or expense in the consolidated statement of operations and comprehensive loss. Unrealized losses not attributable to an expected credit loss and unrealized gains on investments are recorded in other comprehensive income (loss) on the consolidated statements of operations and comprehensive loss. Realized gains and losses, if any, on investments classified as available-for-sale securities are included in other income or expense.

The amortized cost of investments classified as available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. 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.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to a significant concentration of credit risk, consist primarily of cash and cash equivalents and investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits and investments are held.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally two to five years) and generally consist of furniture and fixtures, computers, scientific and office equipment, and in-process costs related to facilities construction. Repairs and maintenance costs are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. If the carrying amount is not recoverable, the Company measures the amount of any impairment by comparing the carrying value of the asset to the present value of the expected future cash flows associated with the use of the asset. While the Company's current and historical operating losses and negative cash flows are indicators of impairment, management believes that future cash flows to be received support the carrying value of its long-lived assets and, accordingly, has not recognized any impairment losses since inception.

Leases

The Company determines if a contract contains a lease at the inception of the contract. The Company currently has leases related to its facilities leased for office and laboratory space, which are classified as operating leases. These leases result in operating right-of-use (ROU) assets, current operating lease liabilities, and non-current operating lease liabilities in the Company's consolidated balance sheets. The Company does not have any financing leases. Leases with a term of 12 months or less are considered short-term and ROU assets and lease obligations are not recognized. Payments associated with short-term leases are expensed on a straight-line basis over the lease term.

Lease liabilities represent an obligation to make lease payments arising from the lease and ROU assets represent the right to use the underlying asset identified in the lease for the lease term. Lease liabilities are measured at the present value of the lease payments not yet paid discounted using the discount rate for the lease established at the lease commencement date. To determine the present value, the implicit rate is used when readily determinable. For those leases where the implicit rate is not provided, the Company determines an incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. ROU assets are measured as the present value of the lease payments and also include any prepaid lease payments made and any other indirect costs incurred, and exclude any lease incentives received. Lease terms may include the impact of options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating leases is recognized on a straight-line basis over the lease term. The Company aggregates all lease and non-lease components for each class of underlying assets into a single lease component.

Revenue Recognition

The Company recognizes revenue in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration the Company is entitled to receive in exchange for such product or service. In doing so, the Company follows a five-step approach: (i) identify the contract 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, and (v) recognize revenue when (or as) the customer obtains control of the product or service. The Company considers the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard. The Company applies the revenue recognition standard, including the use of any practical expedients, consistently to contracts with similar characteristics and in similar circumstances.

A customer is a party that has entered into a contract with the Company, where the purpose of the contract is to obtain a product or a service that is an output of the Company's ordinary activities in exchange for consideration. To be considered a contract, (i) the contract must be approved (in writing, orally, or in accordance with other customary business practices), (ii) each party's rights regarding the product or the service to be transferred can be identified, (iii) the payment terms for the product or the service to be transferred can be identified, (iv) the contract must have commercial substance (that is, the risk, timing or amount of future cash flows is expected to change as a result of the contract), and (v) it is probable that the Company will collect substantially all of the consideration to which it is entitled to receive in exchange for the transfer of the product or the service.

A performance obligation is defined as a promise to transfer a product or a service to a customer. The Company identifies each promise to transfer a product or a service (or a bundle of products or services, or a series of products and services that are substantially the same and have the same pattern of transfer) that is distinct. A product or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) the Company's promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not separately identifiable from other promises in the contract, such promises should be combined into a single performance obligation.

The transaction price is the amount of consideration the Company is entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, the Company considers the existence of any significant financing component, the effects of any variable elements, noncash considerations and consideration payable to the customer. If a significant financing component exists, the transaction price is adjusted for the time value of money. If an element of variability exists, the Company must estimate the consideration it expects to receive and uses that amount as the basis for recognizing revenue as the product or the service is transferred to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts.

If a contract has multiple performance obligations, the Company allocates the transaction price to each distinct performance obligation in an amount that reflects the consideration the Company is entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) the Company transfers control of the product or the service applicable to such performance obligation.

In those instances where the Company first receives consideration in advance of satisfying its performance obligation, the Company classifies such consideration as deferred revenue until (or as) the Company satisfies such performance obligation. In those instances where the Company first satisfies its performance obligation prior to its receipt of consideration, the consideration is recorded as accounts receivable.

The Company expenses incremental costs of obtaining and fulfilling a contract as and when incurred if the expected amortization period of the asset that would be recognized is one year or less, or if the amount of the asset is immaterial. Otherwise, such costs are capitalized as contract assets if they are incremental to the contract and amortized to expense proportionate to revenue recognition of the underlying contract.

Stock Price Appreciation Milestones

The Company estimates the fair value of the stock price appreciation milestones associated with the Amended and Restated Exclusive License Agreement with Memorial Sloan Kettering Cancer Center, using a Monte Carlo simulation model, which relies on the Company's current stock price as well as significant estimates and assumptions to determine the estimated liability associated with the contingent milestone payments. The Company accounts for the fair value of the stock price appreciation milestones in accordance with ASC 815, *Derivatives and Hedging*, with fair value marked to market at each reporting date. The assumptions used to calculate the fair value of the stock price appreciation milestones are subject to a significant amount of judgment including the probability of achieving a specified clinical milestone, the expected volatility of the Company's common stock, the risk-free interest rate, and the estimated term, which is based in part on the last valid patent claim date. The Company remeasures the fair value of the stock price appreciation milestones at each balance sheet date, with changes in fair value recorded in earnings as non-operating income or expense on the consolidated statements of operations and comprehensive loss.

Research and Development Costs

All research and development costs are expensed as incurred.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee stock option and restricted stock unit grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. Performance-based stock units/awards represent a right to receive a certain number of shares of common stock based on the achievement of corporate performance goals and continued employment during the vesting period. At each reporting period, and to the extent achievement of one or any of the performance conditions is probable, we reassess the probability of the achievement of such corporate performance goals and any increase or decrease in share-based compensation expense resulting from an adjustment in the estimated shares to be released is treated as a cumulative catch-up in the period of adjustment. For stock awards for which vesting is subject to both performance-based milestones and market conditions, expense is recorded over the derived service period after the point when the achievement of the performance-based milestone is probable or the performance condition has been achieved.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, with the exception of option grants for which vesting is subject to both performance-based milestones and market conditions, which are valued using a lattice-based model. The fair value of restricted stock units, including performance-based restricted stock units, is based on the closing price of the Company's common stock as reported on The Nasdaq Global Market on the date of grant. The Company recognizes forfeitures for all awards as such forfeitures occur.

Convertible Preferred Stock

The Company applies the relevant accounting standards to distinguish liabilities from equity when assessing the classification and measurement of preferred stock. Preferred shares subject to mandatory redemptions are considered liabilities and measured at fair value. Conditionally redeemable preferred shares are considered temporary equity. All other preferred shares are considered as stockholders' equity.

The Company applies the relevant accounting standards for derivatives and hedging (in addition to distinguishing liabilities from equity) when accounting for hybrid contracts that contain conversion options. Conversion options must be bifurcated from the host instruments and accounted for as free-standing financial instruments according to certain criteria. These criteria include circumstances when (i) the economic characteristics and risks of the embedded derivative instruments are not clearly and closely related to the economic characteristics and risks of the host contract, (ii) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable accounting principles with changes in fair value reported in earnings as they occurred, and (iii) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument. The derivative is subsequently measured at fair value at each reporting date, with the changes in fair value reported in earnings.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more- likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Other comprehensive loss includes unrealized gains and losses, other than losses attributable to a credit loss which are included in other income and expense, on investments classified as available-for-sale securities, which was the only difference between net loss and comprehensive loss for the applicable periods.

Net Loss Per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. The Pre-Funded Warrants associated with the January 2021 public equity offering (see Note 8) are considered outstanding shares in the basic earnings per share calculation given their nominal exercise price. Dilutive common stock equivalents comprise convertible preferred stock, warrants for the purchase of common stock, and common stock options and restricted stock units outstanding under the Company's stock option plans. For all periods presented, there is no difference in the number of common shares used to calculate basic and diluted common shares outstanding due to the Company's net loss position.

Potentially dilutive securities are not included in the calculation of diluted net loss per common share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	As of December 31,		
	2021	2020	2019
Common stock options	7,708,263	10,432,822	9,327,742
Restricted stock units	4,008,832	1,401,732	520,000
Series A convertible preferred stock (if converted)	13,972,745	13,972,745	13,972,745
Total	25,689,840	25,807,299	23,820,487

Going Concern Assessment

Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year from the financial statement issuance date. The Company determined that there are no conditions or events that raise substantial doubt about its ability to continue as a going concern for a period of at least twelve months from the date of issuance of these financial statements.

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments, and amends existing earnings-per-share, or EPS, guidance by requiring that an entity use the if-converted method when calculating diluted EPS for convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years, with early adoption permitted. The Company plans to adopt ASU 2020-06 effective January 1, 2022 and does not anticipate this will have a material effect on the Company's financial statements.

2. Collaboration and License Agreements

Janssen Collaboration and Option Agreement

On April 2, 2020 (the Effective Date), the Company entered into a Collaboration and Option Agreement (the Janssen Agreement) with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Additionally, on the Effective Date, the Company entered into a Stock Purchase Agreement (the Stock Purchase Agreement) with Johnson & Johnson Innovation – JJDC, Inc. (JJDC).

Upon entering the Janssen Agreement, the Company received an upfront, non-refundable and non-creditable payment of $50.0 million. Under the Janssen Agreement, Janssen and the Company will collaborate to develop iPSC-derived CAR NK and CAR T-cell product candidates for the treatment of cancer. Janssen will contribute proprietary antigen binding domains directed to up to four tumor-associated antigen targets (the Janssen Cancer Targets). The Company will research and construct iPSC-derived CAR NK and CAR T-cell product candidates directed to each of the Janssen Cancer Targets (the Collaboration Candidates) and perform preclinical development of Collaboration Candidates. Upon the Company's completion of activities sufficient to allow the filing of an Investigational New Drug (IND) application for a Collaboration Candidate, Janssen will have the right to exercise an exclusive option and obtain an exclusive license to the Company's intellectual property rights for the development and commercialization of such Collaboration Candidate. Upon the exercise of such exclusive option, Janssen will be solely responsible for the worldwide clinical development and commercialization of such Collaboration Candidate, and the Company will be primarily responsible for the manufacture, at Janssen's cost, of such Collaboration Candidate. For each Collaboration Candidate, upon attaining clinical proof-of-concept, the Company shall have the right to elect to co-commercialize and share equally in the profits and losses in the United States, subject to the Company sharing in certain development costs.

Under the terms of the Janssen Agreement, the Company is entitled to receive full funding for all research, preclinical development and IND-enabling activities performed by the Company for Collaboration Candidates, and is eligible to receive (i) with respect to the first Janssen Cancer Target, payments of up to $898.0 million upon the achievement of specified development, regulatory and sales milestones (the Janssen Milestone Payments) for the first Collaboration Candidate, and up to $460.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the first Janssen Cancer Target; and (ii) with respect to each of the second, third and fourth Janssen Cancer Targets, up to $706.0 million in Janssen Milestone Payments for each of the first Collaboration Candidates, and up to $340.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the applicable Janssen Cancer Target, where certain Janssen Milestone Payments under (i) and (ii) are subject to reduction in the event the Company elects to co-commercialize and share equally in the profits and losses in the United States of a respective Collaboration Candidate. The Company is further eligible to receive double-digit tiered royalties ranging up to the mid-teens on net sales of Collaboration Candidates that are commercialized by Janssen under the Janssen Agreement, subject to reduction under certain circumstances.

Under the Stock Purchase Agreement, the Company sold 1.6 million shares of common stock to JJDC at $31.00 per share, for an aggregate purchase price of approximately $50.0 million, on April 7, 2020. The Company determined that this common stock purchase represented a premium of $9.93 per share, or $16.0 million in aggregate (the Equity Premium), and the remaining $34.0 million was recorded as an issuance of common stock in shareholders' equity.

In addition, under the Stock Purchase Agreement, the Company had the right to require JJDC purchase an aggregate of $50.0 million in shares of the Company's common stock in a private placement at the same price per share as that paid by investors in a public offering. In June 2020, in connection with the Company's June 2020 public offering, the Company exercised this right and JJDC purchased in a private placement 1.8 million shares of the Company's common stock at a price of $28.31 per share, for aggregate proceeds of $50.0 million.

Janssen may terminate the Janssen Agreement with respect to one or more Janssen Cancer Targets, or in its entirety, at any time on or after the second anniversary of the Effective Date, and the Company may terminate the Janssen Agreement with respect to a particular Janssen Cancer Target if a Collaboration Candidate has not been selected for IND-enabling studies for such Janssen Cancer Target within specified time periods under certain conditions. The Janssen Agreement contains customary provisions for termination by either party in the event of a material breach of the Janssen Agreement, subject to cure, by the other party and in the event of any bankruptcy, insolvency or similar events with respect to the other party.

The Company applied ASC 808, *Collaborative Arrangements* (ASC 808) and determined the Janssen Agreement is applicable to such guidance. The Company concluded that Janssen represented a customer and applied relevant guidance from ASC 606, *Revenue from Contracts with Customers* (ASC 606) to evaluate the appropriate accounting for the Janssen Agreement. In accordance with this guidance, the Company identified its potential performance obligations, including its grant of a license to Janssen to certain of its intellectual property subject to certain conditions, its conduct of research and development services, and its participation in various joint oversight committees. The Company determined that its grant of a license to Janssen to certain of its intellectual property subject to certain conditions was not distinct from other performance obligations because such grant is dependent on the conduct and results of the research and development services. Accordingly, the Company determined that its grant of a license to Janssen and its conduct of research and development services should be accounted for as one combined performance obligation, and that the combined performance obligation is transferred over the expected term of the conduct of the research and development services, which is estimated to be four years. Additionally, the Company determined that participation in the various joint oversight committees did not constitute a performance obligation as the Company's participation in the various joint oversight committees does not transfer a service.

The Company also assessed the effects of any variable elements under the Janssen Agreement. Such assessment evaluated, among other things, the funding to be received by the Company for its conduct of research and development services. Based on its assessment, the Company concluded that the total amount to be received by the Company for its conduct of research and development services is variable and cannot be readily estimated and, therefore, no amounts associated with such services were included in the initial transaction price. In addition, the Company also assessed its likelihood of receiving (i) preclinical milestones, (ii) various clinical, regulatory and commercial milestone payments, and (iii) royalties on net sales of the Collaboration Candidates. Based on the likelihood of receiving such milestone payments and royalties, no amounts associated with milestones or royalties were included in the initial transaction price.

In accordance with ASC 606, the Company determined that the initial transaction price under the Janssen Agreement equals $66.0 million, consisting of the upfront, non-refundable and non-creditable payment of $50.0 million and the Equity Premium of $16.0 million. The Company concluded that there was not a significant financing component under the Janssen Agreement. The upfront payment of $66.0 million was recorded as deferred revenue and is being recognized as revenue consistent with the Company's efforts related to the conduct of research and development services, as the research and development services are the primary component of the combined performance obligation. Since the total amount to be received by the Company for its research and development services under the Janssen Agreement could not be readily estimated, revenue associated with the upfront payment will be recognized based on actual headcount utilized as a percentage of total headcount expected to be utilized over the expected term of the conduct of the research and development services. Revenue associated with the research and development services will be recognized in an amount equal to the actual costs incurred during the period in which the research and development services are performed by the Company.

During the year ended December 31, 2021, the Company achieved a research milestone under the Janssen Agreement and received a cash payment of $3.0 million. In accordance with ASC 606, the Company determined that the $3.0 million milestone receivable represented an increase in the initial transaction price under the Janssen Agreement in the form of the receipt of variable consideration that was previously constrained. The Company recognized revenue associated with the $3.0 million milestone receivable in an amount equal to the proportional percentage of actual headcount incurred under the Janssen Agreement since its inception as a percentage of the total headcount expected to be utilized over the expected term of conduct of research and development services under the Janssen Agreement. The remaining unrecognized revenue associated with the $3.0 million milestone was recorded to deferred revenue, and is being recognized as revenue over the expected term of conduct of research and development services.

As a direct result of the Company's entry into the Janssen Agreement, the Company incurred $13.6 million in sublicense fees to certain of its existing licensors. The $13.6 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs* (ASC 340) and is amortized to research and development expense ratably with the Company's revenue recognition

under the Janssen Agreement. During the year ended December 31, 2021, the Company recognized $1.7 million of such expense. As of December 31, 2021, the Janssen Agreement contract asset balance was $9.5 million.

The Company recognized revenue of $43.7 million under the Janssen Agreement for the year ended December 31, 2021. Such revenue comprised $29.5 million associated with research and development services and $14.2 million associated with the upfront fee and Equity Premium for the year ended December 31, 2021. The Company recognized revenue of $16.8 million under the Janssen Agreement for the year ended December 31, 2020. Such revenue comprised $10.3 million associated with research and development services and $6.5 million associated with the upfront fee and Equity Premium for the year ended December 31, 2020. As of December 31, 2021, aggregate deferred revenue related to the Janssen Agreement was $48.3 million, of which $21.2 million is classified as current.

As of December 31, 2021, the Company has received $31.1 million in cash in aggregate research and development fees from Janssen.

Ono Collaboration and Option Agreement

On September 14, 2018, the Company entered into a Collaboration and Option Agreement (the Ono Agreement) with Ono Pharmaceutical Co. Ltd. (Ono) for the joint development and commercialization of two off-the-shelf iPSC-derived chimeric antigen receptor (CAR) T-cell product candidates. The first off-the-shelf, iPSC-derived CAR T-cell candidate (Candidate 1) targets an antigen expressed on certain lymphoblastic leukemias, and the second off-the-shelf, iPSC-derived CAR T-cell candidate (Candidate 2) targets a novel antigen identified by Ono expressed on certain solid tumors (each a Candidate and collectively the Candidates).

On December 4, 2020, the Company and Ono entered into a letter agreement (the Ono Letter Agreement) in connection with the Ono Agreement. Pursuant to the Ono Letter Agreement, Ono delivered to the Company proprietary antigen binding domains targeting an antigen expressed on certain solid tumors and nominated such antigen binding domains as the Ono Antigen Binding Domain for incorporation into Collaboration Candidate 2. In connection with such nomination and pursuant to the original agreement, in December 2020, Ono paid the Company a milestone fee of $10.0 million for further research and development of Collaboration Candidate 2 and Ono maintains its option to this candidate. In addition, in connection with the Ono Letter Agreement, Fate and Ono agreed to the termination of the Ono Agreement with respect to Collaboration Candidate 1. Fate retains all rights, in its sole discretion, to research, develop and commercialize Collaboration Candidate 1 throughout the world without any obligation to Ono.

Pursuant to the Ono Agreement, the Company and Ono are jointly conducting research and development activities under a joint development plan, with the goal of advancing Candidate 2 to a pre-defined preclinical milestone. The Company has granted to Ono, during a specified period of time, an option to obtain an exclusive license under certain intellectual property rights to develop and commercialize Candidate 2 in all territories of the world, with the Company retaining the right to co-develop and co-commercialize Candidate 2 in the United States and Europe under a joint arrangement whereby it is eligible to share at least 50% of the profits and losses (the Option).

The Option will expire upon the earliest of: (a) the achievement of the pre-defined preclinical milestone, (b) termination by Ono of research and development activities for the Candidate and (c) the date that is the later of (i) four years after the Effective Date and (ii) completion of all applicable activities contemplated under the joint development plan (the Option Period). The Company has maintained worldwide rights of manufacture for Candidate 2.

Under the terms of the Ono Agreement, Ono paid the Company an upfront, non-refundable and non-creditable payment of $10.0 million in connection with entering into the agreement. Additionally, as consideration for the Company’s conduct of research and preclinical development under a joint development plan, Ono pays the Company annual research and development fees set forth in the annual budget included in the joint development plan, which fees are estimated to be $20.0 million in aggregate over the course of the joint development plan.

Further, under the terms of the Ono Agreement, Ono has agreed to pay the Company up to an additional $20.0 million, subject to the exercise by Ono of the Option (Option Exercise Fees) during the Option Period for Candidate 2. Such fees are in addition to the upfront payment research and development fees, and the previously paid $10.0 milestone associated with the Ono Letter Agreement.

Subject to Ono’s exercise of the Option and to the achievement of certain clinical, regulatory and commercial milestones (Milestones) with respect to the Candidate in specified territories, the Company is entitled to receive an aggregate of up to $885.0 million in additional milestone payments for Candidate 2, with the applicable milestone payments for Candidate 2 for the United States and Europe subject to reduction by 50% if the Company elects to co-develop and co-commercialize Candidate 2 as described above. The Company is also eligible to receive tiered royalties (Royalties) ranging from the mid-single digits to the low-double digits based on annual net sales by Ono for Candidate 2 in specified territories, with such royalties subject to certain reductions.

No milestone payments specific to Candidate 1 are payable under the Ono Agreement, given the termination of such candidate in December 2020 under the agreement.

The Ono Agreement will terminate with respect to a Candidate if Ono does not exercise its Option for a Candidate within the Option Period, or in its entirety if Ono does not exercise any of its Options for the Candidates within their respective Option Periods. In addition, either party may terminate the Ono Agreement in the event of breach, insolvency or patent challenges by the other party; provided, that Ono may terminate the Ono Agreement in its sole discretion (x) on a Candidate-by-Candidate basis at any time after the second anniversary of the effective date of the Ono Agreement or (y) on a Candidate-by-Candidate or country-by-country basis at any time after the expiration of the Option Period, subject to certain limitations. The Ono Agreement will expire on a Candidate-by-Candidate and country-by-country basis upon the expiration of the applicable royalty term, or in its entirety upon the expiration of all applicable payment obligations under the Ono Agreement.

The Company applied ASC 808 to the Ono Agreement and Ono Letter Agreement and determined that the agreements are applicable to such guidance. The Company concluded that Ono represented a customer and applied relevant guidance from ASC 606 to evaluate the appropriate accounting for the Ono Agreement and the Ono Letter Agreement. In accordance with this guidance, the Company identified its performance obligations, including its grant of a license to Ono to certain of its intellectual property subject to certain conditions, its conduct of research services, and its participation in a joint steering committee. The Company determined that its grant of a license to Ono to certain of its intellectual property subject to certain conditions was not distinct from other performance obligations because such grant is dependent on the conduct and results of the research services. Additionally, the Company determined that its conduct of research services was not distinct from other performance obligations since such conduct is dependent on the guidance of the joint steering committee. Accordingly, the Company determined that all performance obligations should be accounted for as one combined performance obligation, and that the combined performance obligation is transferred over the expected term of the conduct of the research services, which is estimated to be four years. The termination of Candidate 1 under the Ono Agreement did not impact this assessment.

The Company also assessed, in connection with the upfront, non-refundable and non-creditable payment of $10.0 million received in September 2018 and the $5.0 million prepayment of the first-year research and development fees in October 2018 and concluded that there was not a significant financing component to the Ono Agreement.

The Company also assessed the effects of any variable elements under the Ono Agreement. Such assessment evaluated, among other things, the likelihood of receiving (i) preclinical milestone and option fees, (ii) various clinical, regulatory and commercial milestone payments, and (iii) royalties on net sales of either product Candidate. Based on its assessment, the Company concluded that, based on the likelihood of these variable components occurring, there was not a significant variable element included in the transaction price. Accordingly, the Company has not assigned a transaction price to any Ono Option Milestone, Ono Milestones or Ono Option Exercise Fees, other than the $10.0 million milestone triggered as part of the Ono Letter Agreement in December 2020, given the substantial uncertainty related to their achievement and has not assigned a transaction price to any Ono Royalties.

In accordance with ASC 606, the Company determined that the initial transaction price under the Ono Agreement equals $30.0 million, consisting of the upfront, non-refundable and non-creditable payment of $10.0 million and the aggregate estimated research and development fees of $20.0 million. The upfront payment of $10.0 million was recorded as deferred revenue and is being recognized as revenue over time in conjunction with the Company's conduct of research services as the research services are the primary component of the combined performance obligations. Revenue associated with the upfront payment will be recognized based on actual costs incurred as a percentage of the estimated total costs expected to be incurred over the expected term of conduct of the research services. The Company recorded the $5.0 million prepayment of the first-year research and development fees as deferred revenue, and such fees were recognized as revenue as the research services were delivered.

In accordance with ASC 606, the Company concluded that the $10.0 million milestone payment associated with the Ono Letter Agreement represented an increase in the initial transaction price under the Ono Agreement in the form of the receipt of variable consideration that was previously constrained. The milestone payment of $10.0 million was recorded to deferred revenue for the proportional percentage of remaining costs to be incurred under the Ono Agreement as a percentage of the estimated total costs expected to be incurred over the expected term of conduct of the research services and is being recognized as revenue over the expected term in conjunction with the Company's conduct of research services as the research services are the primary component of the combined performance obligations. The Company recognized revenue associated with the milestone payment for the proportional percentage of actual costs incurred under the Ono Agreement as a percentage of the estimated total costs expected to be incurred over the expected term of conduct of the research services.

As a direct result of the Company's entry into the Ono Agreement and the Ono Letter Agreement, the Company incurred an aggregate of $4.0 million in sublicense consideration to existing licensors of the Company. The $4.0 million in sublicense consideration represents an asset under ASC 340 and is being amortized to research and development expense ratably with the Company's revenue recognition under the Ono Agreement. During the years ended December 31, 2021 and 2020, the Company recognized $1.2 million and $1.8 million, respectively, of such expense. As of December 31, 2021, the Ono Agreement contract asset had a balance of $0.3 million.

The Company recognized revenue of $12.1 million, $14.6 million, and $9.3 million under the Ono Agreement and Ono Letter Agreement during the years ended December 31, 2021, 2020 and 2019, respectively. Such revenue comprised $6.0 million associated

with research services and $6.1 million associated with the upfront payment during the year ended December 31, 2021. Such revenue comprised $6.1 million associated with the Ono Letter Agreement milestone earned in December 2020, $5.7 million associated with research services and $2.8 million associated with the upfront payment during the year ended December 31, 2020. Such revenue comprised $6.2 million associated with research services and $3.1 million associated with the upfront payment during the year ended December 31, 2019. As of December 31, 2021, aggregate deferred revenue related to the Ono Agreement and Ono Letter Agreement was $0.3 million, all of which is classified as current.

As of December 31, 2021, the Company has received $17.0 million in cash of aggregate research and development fees from Ono.

Memorial Sloan Kettering Cancer Center License Agreement

On May 15, 2018, the Company entered into an Amended and Restated Exclusive License Agreement (the Amended MSK License) with Memorial Sloan Kettering Cancer Center (MSK). The Amended MSK License amends and restates the Exclusive License Agreement entered into between the Company and MSK on August 19, 2016 (the Original MSK License), pursuant to which the Company entered into an exclusive license agreement with MSK for rights relating to compositions and methods covering iPSC-derived cellular immunotherapy, including T-cells and NK-cells derived from iPSCs engineered with CARs.

Pursuant to the Amended MSK License, MSK granted to the Company additional licenses to certain patents and patent applications relating to new CAR constructs and off-the-shelf CAR T cells, including the use of clustered regularly interspaced short palindromic repeat (CRISPR) and other innovative technologies for their production, in each case to research, develop, and commercialize licensed products in the field of all human therapeutic uses worldwide. The Company has the right to grant sublicenses to certain licensed rights in accordance with the terms of the Amended MSK License, in which case it is obligated to pay MSK a percentage of certain sublicense income received by the Company.

The Company is obligated to pay to MSK an annual license maintenance fee during the term of the agreement, and milestone payments upon the achievement of specified clinical, regulatory and commercial milestones for licensed products as well as royalty payments on net sales of licensed products

In the event a licensed product achieves a specified clinical milestone, MSK is then eligible to receive certain milestone payments totaling up to $75.0 million based on the price of the Company’s common stock, where the amount of such payments owed to MSK is contingent upon certain increases in the price of the Company’s common stock following the date of achievement of such clinical milestone. These payments are based on common stock price multiples, with the numerator being the fair value of the ten-trading day trailing average closing price of the Company’s common stock and the denominator being the ten-trading day trailing average closing price of the Company’s common stock as of the effective date of the Amended MSK License, adjusted for any stock splits, cash dividends, stock dividends, other distributions, combinations, recapitalizations, or similar events. Under the terms of the Amended MSK License, upon a change of control of the Company, in certain circumstances, the Company may be required to pay a portion of these payments to MSK based on the price of the Company’s common stock in connection with such change of control.

The following table summarizes the common stock multiples and the stock price appreciation milestone payments under the terms of the agreement:

Common stock multiple		5.0x		10.0x		15.0x
Ten-trading day trailing average common stock price	$	50.18	$	100.36	$	150.54
Stock price appreciation milestone payment (in millions)	$	20.0	$	30.0	$	25.0

In July 2021, the Company achieved the specified clinical milestone for a licensed product under the Amended MSK License and the Company’s ten-trading day trailing average common stock price exceeded the first, pre-specified threshold. As a result, the Company remitted the first milestone payment of $20.0 million to MSK during the year ended December 31, 2021.

To determine the estimated fair value of the remaining stock price appreciation milestones, the Company uses a Monte Carlo simulation methodology which models future Company common stock prices based on the current stock price and several key variables. The following variables were incorporated in the calculation of the estimated fair value of the stock price appreciation milestones as of December 31, 2021:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Risk-free interest rate	1.7%	1.5%
Expected volatility	77.6%	78.1%
Estimated term (in years)	17.0	18.0
Closing stock price as of measurement date	$ 58.51	$ 90.93

The key inputs to the Monte Carlo simulation to determine the fair value of the stock price appreciation milestones include the Company's stock price as of the measurement date; the estimated term which is based in part on the last valid patent claim date; the expected volatility of the Company's common stock, estimated using the Company's historical common stock volatility as of the remeasurement date; and the risk-free rate based on the U.S. Treasury yield for the estimated term determined. Fair value measurements are highly sensitive to changes in these inputs and significant changes could result in a significantly higher or lower fair value and resulting expense or gain.

At each balance sheet date, the Company remeasures the fair value of the stock price appreciation milestones, with changes in fair value recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive loss. Amounts are included in current or non-current liabilities based on the estimated timeline associated with the individual potential payments. During the year ended December 31, 2021 and 2020, the Company recorded $3.5 million of income and $47.7 million of expense, respectively, associated with the change in fair value of the stock price appreciation milestones. No income or expense was recorded during the year ended December 31, 2019. As of December 31, 2021 and 2020, the Company recorded a liability of $24.2 million and $47.7 million, respectively, associated with the stock price appreciation milestones for the Amended MSK License.

Juno Collaboration and License Agreement

On May 4, 2015, the Company entered into a strategic research collaboration and license agreement (the Juno Agreement) with Juno Therapeutics, Inc. (Juno) to screen for and identify small molecules that enhance the therapeutic properties of Juno's genetically-engineered T-cell immunotherapies. The four-year initial research term under the Juno Agreement concluded as scheduled on May 4, 2019, and the overall agreement was terminated upon the receipt of the last quarterly research payment of $0.2 million, which occurred in May 2019.

The Company applied ASC 606 to evaluate the appropriate accounting for the Juno Agreement. In accordance with this guidance, the Company identified its performance obligations, including its grant of an exclusive worldwide license to certain of its intellectual property subject to certain conditions, its conduct of research services and its participation in a joint research committee.

No revenue was recognized under the Juno Agreement during the years ended December 31, 2021, and 2020. Total revenue recognized under the Juno Agreement during the year ended December 31, 2019 was $1.4 million, which comprised $0.7 million associated with the upfront fee and equity premium, and $0.7 million associated with research services.

3. California Institute for Regenerative Medicine Award

On April 5, 2018, the Company executed an award agreement with the California Institute for Regenerative Medicine (CIRM) pursuant to which CIRM awarded the Company $4.0 million to advance the Company's FT516 product candidate into a first-in-human clinical trial for the treatment of subjects with advanced solid tumors, including in combination with monoclonal antibody therapy (the Award). Pursuant to the terms of the Award, the Company is eligible to receive five disbursements in varying amounts totaling $4.0 million, with one disbursement receivable upon the execution of the Award, and four disbursements receivable upon the completion of certain milestones throughout the project period. The Award is subject to certain co-funding requirements by the Company, and the Company is required to provide CIRM progress and financial update reports under the Award.

Pursuant to the terms of the Award, the Company, in its sole discretion, has the option to treat the Award either as a loan or as a grant. In the event the Company elects to treat the Award as a loan, the Company will be obligated to repay i) 60%, ii) 80%, iii) 100% or iv) 100% plus interest at 7% plus LIBOR, of the total Award to CIRM, where such repayment rate is dependent upon the phase of clinical development of FT516 at the time of the Company's election. If the Company does not elect to treat the Award as a loan within 10 years of the date of the Award, the Award will be considered a grant and the Company will be obligated to pay to CIRM a royalty on commercial sales of FT516 until such royalty payments equal nine times the total amount awarded to the Company under the Award.

Since the Company may, at its election, repay some or all of the Award, the Company accounts for the Award as a liability until the time of election. As of December 31, 2021, the Company has received all disbursements available under the Award in the amount of $4.0 million. The aggregate amount received is recorded as a CIRM Liability on the accompanying consolidated balance sheets and classified as current or non-current based on the potential amount payable within twelve months of the current balance sheet date.

4. Investments

The Company invests portions of excess cash in United States treasuries, commercial paper, non-U.S. government securities, municipal securities, and corporate debt securities with maturities ranging from three to eighteen months from the purchase date. These investments are accounted for as available-for-sale securities and are classified as short-term and long-term investments in the accompanying consolidated balance sheets based on each security's contractual maturity date.

The following table summarizes the Company's investments accounted for as available-for-sale securities as of December 31, 2021 and 2020 (in thousands):

	Maturity (in years)	Amortized Cost	Unrealized Losses	Unrealized Gains	Estimated Fair Value
December 31, 2021					
Classified as current assets:					
U.S. Treasury debt securities	1 or less	$ 70,653	$ (163)	$ —	$ 70,490
Municipal securities	1 or less	18,017	(6)	1	18,012
Corporate debt securities	1 or less	169,736	(187)	—	169,549
Commercial paper	1 or less	224,333	(59)	2	224,276
Total short-term investments		$ 482,739	$ (415)	$ 3	$ 482,327
Classified as non-current assets:					
U.S. Treasury debt securities	Greater than 1	$ 9,989	$ (35)	$ —	$ 9,954
Municipal securities	Greater than 1	9,034	(42)	—	8,992
Corporate debt securities	Greater than 1	81,989	(271)	—	81,718
Total long-term investments		$ 101,012	$ (348)	$ —	$ 100,664
December 31, 2020					
Classified as current assets:					
U.S. Treasury debt securities	1 or less	$ 39,736	$ —	$ 31	$ 39,767
Non-U.S. government securities	1 or less	5,054	—	2	$ 5,056
Municipal securities	1 or less	3,082	(1)	—	$ 3,081
Corporate debt securities	1 or less	159,947	(68)	124	$ 160,003
Commercial paper	1 or less	107,680	(18)	—	$ 107,662
Total short-term investments		$ 315,499	$ (87)	$ 157	$ 315,569

As of December 31, 2021 and 2020, the Company had $1.1 million and $1.5 million, respectively, of accrued interest on investments recorded in prepaid expenses and other assets on the consolidated balance sheets.

The following tables present gross unrealized losses and fair values for those investments that were in an unrealized loss position as of December 31, 2021 and December 31, 2020, aggregated by investment category and the length of time that individual securities have been in a continuous loss position (in thousands):

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
December 31, 2021						
U.S. Treasury debt securities	$ 80,444	$ (198)	$ —	$ —	$ 80,444	$ (198)
Municipal securities	23,352	(48)	—	—	23,352	(48)
Corporate debt securities	250,467	(458)	—	—	250,467	(458)
Commercial paper	59,863	(59)	—	—	59,863	(59)
Total	$ 414,126	$ (763)	$ —	$ —	$ 414,126	$ (763)
December 31, 2020						
Municipal securities	$ 3,081	$ (1)	$ —	$ —	$ 3,081	$ (1)
Corporate debt securities	108,147	(68)	—	—	108,147	(68)
Commercial paper	55,688	(18)	—	—	55,688	(18)
Total	$ 166,916	$ (87)	$ —	$ —	$ 166,916	$ (87)

The Company reviews its investment holdings at the end of each reporting period and evaluates any unrealized losses using the expected credit loss model to determine if the unrealized loss is a result of a credit loss or other factors. The Company also evaluates its investment holdings for impairment using a variety of factors including the Company's intent to sell the underlying securities prior to maturity and whether it is more likely than not that the Company would be required to sell the securities before the recovery of their amortized basis. During the years ended December 31, 2021, 2020 and 2019, the Company did not recognize any impairment or realized gains or losses on sales of investments, and the Company did not record an allowance for, or recognize, any expected credit losses.

5. Fair Value Measurements

The following tables presents the Company's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2021 and 2020 (in thousands):

		Fair Value Measurements at Reporting Date Using		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2021:				
Financial assets:				
Money market funds	$ 133,583	$ 133,583	$ —	$ —
U.S. Treasury debt securities	80,444	80,444	—	—
Municipal securities	27,004	—	27,004	—
Corporate debt securities	251,267	—	251,267	—
Commercial paper	224,276	—	224,276	—
Total assets measured at fair value on a recurring basis	$ 716,574	$ 214,027	$ 502,547	$ —
Financial liabilities:				
Stock price appreciation milestones	$ 24,168	$ —	$ —	$ 24,168
Total financial liabilities measured at fair value on a recurring basis	$ 24,168	$ —	$ —	$ 24,168
As of December 31, 2020:				
Financial assets:				
Money market funds	$ 167,347	$ 167,347	$ —	$ —
U.S. Treasury debt securities	39,767	39,767	—	—
Non-U.S. government securities	5,056	—	5,056	—
Municipal securities	3,081	—	3,081	—
Corporate debt securities	160,003	—	160,003	—
Commercial paper	107,662	—	107,662	—
Total assets measured at fair value on a recurring basis	$ 482,916	$ 207,114	$ 275,802	$ —
Financial liabilities:				
Stock price appreciation milestones	$ 47,702	$ —	$ —	$ 47,702
Total financial assets measured at fair value on a recurring basis	$ 47,702	$ —	$ —	$ 47,702

Level 1 assets consisted of money market funds and U.S. Treasury securities measured at fair value based on quoted prices in active markets as provided by the Company's investment managers.

Level 2 assets consisted of corporate debt securities, commercial paper, municipal securities, and non-U.S. government securities measured at fair value using standard observable inputs, including reported trades, broker/dealer quotes, and bids and/or offers. The Company validates the quoted market prices provided by its investment managers by comparing the investment managers' assessment of the fair values of the Company's investment portfolio balance against the fair values of the Company's investment portfolio balance obtained from an independent source.

There were no Level 3 assets held by the Company as of December 31, 2021.

Level 3 liabilities consisted of stock price appreciation milestones associated with the Amended MSK License as described in detail in Note 2. To determine the estimated fair value of the stock price appreciation milestones, the Company uses a Monte Carlo simulation methodology which models future Company common stock prices based on several key variables. The assumptions used to calculate the fair value of the stock price appreciation milestones are subject to a significant amount of judgment including the expected volatility of the Company's common stock and estimated term, which is based in part on the last valid patent claim date. Fair value measurements are highly sensitive to changes in these inputs and significant changes could result in a significantly higher or

lower fair value and resulting expense or gain. Further, as the stock price appreciation milestones are first contingent upon the achievement of a specified clinical milestone, the Company also estimates the fair value of the stock price appreciation milestones based on the probability of achieving the clinical milestone. This assessment is based on several factors including the successful achievement of technological, manufacturing, and regulatory requirements.

A small change in the assumptions and other inputs, such as the price of the Company's common stock, may have a relatively large change in the estimated fair value of the stock price appreciation milestones and associated liability and expense. For example, keeping all other variables constant, a hypothetical 10% increase in the stock price at December 31, 2021 from $58.51 to $64.36 per share would have decreased the income recorded during 2021 by $2.4 million related to the stock price appreciation milestones. Keeping all other variables constant, a hypothetical 10% decrease in the stock price at December 31, 2021 from $58.51 to $52.66 per share would have increased the income recorded during 2021 by $2.3 million related to the stock price appreciation milestones.

The following table presents the changes in fair value of the Company's Level 3 stock price appreciation milestones liability (in thousands):

Balance at December 31, 2020	$ 47,702
Achievement of $20.0 million stock price appreciation milestone	(20,000)
Changes in fair value of stock price appreciation milestones liability	(3,534)
Balance at December 31, 2021	$ 24,168

None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

6. Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31,	
	2021	2020
Furniture and fixtures	$ 1,209	$ 803
Computer and office equipment	2,168	656
Software	1,899	257
Leasehold improvements—building	52,948	2,701
Scientific equipment	50,250	20,794
Construction-in-process	—	18,192
Total property and equipment, gross	108,474	43,403
Less accumulated depreciation and amortization	(16,945)	(11,095)
Total property and equipment, net	$ 91,529	$ 32,308

Depreciation expense related to property and equipment was $5.9 million, $3.1 million, and $2.2 million, for the years ended December 31, 2021, 2020, and 2019, respectively. No material gains or losses on the disposal of property and equipment have been recorded for the years ended December 31, 2021, 2020, and 2019.

7. Accrued Expenses and Long-Term Debt

Accrued Expenses

Current accrued expenses consist of the following (in thousands):

	December 31,	
	2021	2020
Accrued payroll and other employee benefits	$ 18,358	$ 4,815
Accrued clinical trial related costs	12,344	5,244
Accrued other	11,710	5,505
Total current accrued expenses	$ 42,412	$ 15,564

Long-Term Debt

Silicon Valley Bank Debt Facilities

In 2009, the Company entered into a Loan and Security Agreement with Silicon Valley Bank, which was collateralized by substantially all of the Company's assets excluding certain intellectual property. This Loan and Security Agreement was subsequently amended in 2014 and 2017. In November 2019, the Company repaid in full all outstanding obligations under the Loan and Security Agreement, as amended. The Company used cash on hand in the amount of $14.2 million for the repayment of such obligations, including the repayment of $13.0 million in principal and $1.2 million associated with the final fee and outstanding interest.

For the year ended December 31, 2019, the Company recorded $1.8 million in aggregate interest expense related to the Loan and Security Agreement.

8. Leases

The Company has lease agreements for office, laboratory and manufacturing spaces that are classified as operating leases on the consolidated balance sheets. These leases have terms varying from one to approximately sixteen years, with renewal options of up to ten years, as well as early termination options. Extension and termination options are included in the total lease term when the Company is reasonably certain to exercise them. The leases are subject to additional variable charges, including common area maintenance, property taxes, property insurance and other variable costs. Given the variable nature of such costs, they are recognized as expense as incurred. Additionally, some of the Company's leases are subject to certain fixed fees which the Company has determined to be non-lease components. The Company has elected to combine and account for lease and non-lease components as a single lease component for purposes of determining the total future lease payments.

In January 2020, the Company entered into a lease agreement for certain office, laboratory and manufacturing space (the Premises), and such lease is accounted for as an operating lease. The Premises are located in San Diego, California and the Company moved its corporate headquarters to the Premises in August 2021. Lease payments commenced in May 2021 (the Rent Commencement Date) and the lease has a lease term of 15 years starting from the Rent Commencement Date. The Company has the option to extend the lease for two successive five-year periods. The Company also has a one-time option to terminate the lease after 10 years from the Rent Commencement Date, subject to payment of a $30.0 million early termination fee. The landlord of the Premises is obligated to contribute an aggregate of up to $29.8 million toward tenant improvements of the Premises. As of December 31, 2021, the Company had utilized the entire tenant improvements allowance. The Company recorded the tenant improvement allowance as part of the Company's leasehold improvements, which is depreciated in accordance with the Company's Property and Equipment policy. In connection with the lease, the Company maintains a letter of credit for the benefit of the landlord in an amount equal to $15.0 million, which amount is subject to reduction over time.

In November 2021, the Company entered into a lease agreement for certain office space in San Diego, California, and such lease is accounted for as an operating lease. Lease payments shall commence, subject to certain conditions, in January 2022 (the Rent Commencement Date) and the lease has a lease term of 6 years starting from the Rent Commencement Date. The Company has no option to extend the lease, and no option to early terminate the lease. Upon lease commencement in December 2021, the Company recorded a right-of-use asset of $6.0 million.

As of December 31, 2021, future undiscounted minimum contractual payments under the Company's operating leases were $192.6 million, which will be paid over a remaining weighted-average lease term of 12.3 years. The weighted-average discount rate for the operating lease liabilities was 6.94%, which was the Company's incremental borrowing rate at lease commencement, as the discount rates implicit in the leases could not be readily determined.

The components of lease expense for the years ended December 31, 2021, 2020, and 2019 were as follows (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Straight-line lease expense	$ 15,354	$ 12,076	$ 3,781
Variable lease expense	1,660	2,245	2,330
Total operating lease expense	$ 17,014	$ 14,321	$ 6,111

No short-term lease expense was recognized in the year ended December 31, 2021. Total short-term lease expense associated with short-term leases for the years ended December 31, 2020, and 2019 was $1.2 million and $1.1 million, respectively.

Future undiscounted minimum payments under the Company's operating leases as of December 31, 2021 are as follows (in thousands):

	Operating Lease Payments
Years Ending December 31,	
2022	$ 14,970
2023	14,498
2024	14,836
2025	15,087
2026	15,540
2027	16,006
Thereafter	101,635
Total undiscounted lease payments	$ 192,573
Less: imputed interest	(77,755)
Total lease liability	$ 114,818

9. Convertible Preferred Stock and Stockholders' Equity

Convertible Preferred Stock

In November 2016, the Company completed a private placement of stock in which investors, including investors affiliated with the directors and officers of the Company, purchased convertible preferred stock and common stock of the Company (the November 2016 Placement). The Company issued 2,819,549 shares of non-voting Class A Convertible Preferred Stock (the Class A Preferred) at $13.30 per share, each of which is convertible into five shares of common stock upon certain conditions defined in the Certificate of Designation of Preferences, Rights and Limitations of the Class A Preferred filed with the Delaware Secretary of State on November 22, 2016 (the CoD). The Class A Preferred were purchased exclusively by entities affiliated with Redmile Group, LLC (collectively, Redmile). The terms of the CoD prohibited Redmile from converting the Class A Preferred into shares of the Company's common stock if, as a result of conversion, Redmile, together with its affiliates, would own more than 9.99% of the Company's common stock then issued and outstanding (the Redmile Percentage Limitation), which percentage could change at Redmile's election upon 61 days' notice to the Company to (i) any other number less than or equal to 19.99% or (ii) subject to approval of the Company's stockholders to the extent required in accordance with the NASDAQ Global Market rules, any number in excess of 19.99%. On May 2, 2017, the Company's stockholders approved the issuance of up to an aggregate of 14,097,745 shares of common stock upon the conversion of the outstanding shares of Class A Preferred. As a result, Redmile has the right to increase the Redmile Percentage Limitation to any percentage in excess of 19.99% at its election. The Company also issued 7,236,837 shares of common stock at $2.66 per share as part of the November 2016 Placement.

The Class A Preferred are non-voting shares and have a stated par value of $0.001 per share and are convertible into five shares of the Company's common stock at a conversion price of $2.66 per share, which was the fair value of the Company's common stock on the date of issuance. Holders of the Class A Preferred have the same dividend rights as holders of the Company's common stock. Additionally, the liquidation preferences of the Class A Preferred are *pari passu* among holders of the Company's common stock and holders of the Class A Preferred, pro rata based on the number of shares held by each such holder (treated for this purpose as if the Class A Preferred had been converted to common stock).

During the year ended December 31, 2019, 25,000 shares of the Company's Class A Preferred were converted into 125,000 shares of the Company's common stock.

Description of Securities

Dividends

As of December 31, 2021, the Board of Directors of the Company has not declared any dividends.

2013 Stock Option and Incentive Plan, and Inducement Equity Plan

2013 Stock Option and Incentive Plan

On August 28, 2013, the Company's board of directors and stockholders approved and adopted the 2013 Stock Option and Incentive Plan (the 2013 Plan). The 2013 Plan became effective immediately prior to the Company's IPO. The 2013 Plan was

subsequently amended in May 2017. Under the 2013 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, directors or consultants of the Company or its subsidiaries. A total of 1,020,000 shares of common stock were initially reserved for issuance under the 2013 Plan, and in May 2017, stockholders approved an additional 2,500,000 shares of common stock for issuance under the 2013 Plan. The shares issuable pursuant to awards granted under the 2013 Plan will be authorized, but unissued shares. The shares of common stock underlying any awards from the 2013 Plan and a previously existing equity plan from 2007 that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of common stock, expire or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2013 Plan.

In addition, the number of shares of stock available for issuance under the 2013 Plan will be automatically increased each January 1 by 4% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31 or such lesser number as determined by the compensation committee of the Company's board of directors.

Recipients of stock options under the 2013 Plan shall be eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair value of such stock on the date of grant. Under the 2013 Plan, stock options generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years, or vest monthly over four years, unless they contain specific performance and/or market-based vesting provisions. The maximum term of stock options granted under the 2013 Plan is ten years. Under the 2013 Plan, restricted stock units generally vest annually over four years. Performance-based stock units/awards vest upon the achievement of certain pre-defined company-specific performance-based clinical achievement criteria.

Inducement Plan

On May 10, 2016, the Company's board of directors approved the Fate Therapeutics, Inc. Inducement Equity Plan (the Inducement Plan), the purpose of which is to enable the Company to grant equity awards to induce highly-qualified prospective officers and employees who are not employed by the Company to accept employment with the Company. Under the Inducement Plan, the Company may grant non-qualified stock options and restricted stock units. A total of 500,000 shares of common stock were initially reserved for issuance under the Inducement Plan. In January 2021, March 2020, and January 2019, an additional 300,000 shares, 470,822 shares, and 200,000 shares, respectively, of common stock were reserved for issuance under the Inducement Plan. The shares of common stock underlying any awards from the Inducement Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of common stock, expire or are otherwise terminated (other than by exercise) under the Inducement Plan will be added back to the shares of common stock available for issuance under the Inducement Plan.

Employee Stock Purchase Plan

On September 13, 2013, the Company's board of directors approved and adopted the 2013 Employee Stock Purchase Plan (the ESPP). A total of 729,000 shares of common stock were initially reserved for issuance under the ESPP. In addition, the number of shares of stock available for issuance under the ESPP will be automatically increased each January 1, beginning on January 1, 2015, by the lesser of (i) 2% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31, (ii) 450,000 shares, or (iii) such lesser number as determined by the compensation committee of the Company's board of directors.

No purchases have been made to date under the ESPP.

Pre-Funded Warrants

In January 2021, in conjunction with a public offering, the Company issued Pre-Funded Warrants, in lieu of common stock to certain investors, to purchase 257,310 shares of the Company's common stock. The purchase price for the Pre-Funded Warrants was $85.499 per Pre-Funded Warrant, which equals the per share public offering price for the shares of common stock less the $0.001 exercise price for each such Pre-Funded Warrant. Given that the Pre-Funded Warrants are indexed to the Company's own shares of common stock (and otherwise meet the requirements to be classified in equity), the Company recorded the consideration received from the issuance of the warrants as additional paid-in capital on the Company's consolidated balance sheets.

The Pre-Funded Warrants are exercisable at any time after the date of issuance. A holder of Pre-Funded Warrants may not exercise the Pre-Funded Warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise. A holder of Pre-Funded Warrants may increase or decrease this percentage not in excess of 19.99% by providing at least 61 days' prior notice to the Company.

As of December 31, 2021, there were 257,310 Pre-Funded Warrants outstanding.

Stock Options and Restricted Stock Unit Awards

Stock Options. The following table summarizes stock option activity and related information under all equity plans for the year ended December 31, 2021:

	Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in 000s)
Outstanding at December 31, 2020	10,432,822	$ 15.11		
Granted	409,582	90.10		
Exercised	(2,430,298)	8.55		
Cancelled	(703,843)	23.11		
Outstanding at December 31, 2021	7,708,263	$ 20.43	6.71	$ 305,706
Options vested and expected to vest at December 31, 2021	7,708,263	$ 20.43	6.71	$ 305,706
Options exercisable at December 31, 2021	5,297,524	$ 14.10	6.09	$ 236,754

For the years ended December 31, 2021, 2020, and 2019, the weighted average grant date fair value of stock options granted per share was equal to $55.83, $18.87 and $11.52, respectively.

As of December 31, 2021, 2020 and 2019, the unrecognized compensation cost related to outstanding options was $48.9 million, $66.1 million and $40.4 million, respectively, which was expected to be recognized as expense over approximately 2.3 years, 2.9 years and 2.9 years, respectively.

The total intrinsic value, which is the amount by which the exercise price was exceeded by the price of the Company's common stock on the date of exercise, of stock options exercised during the years ended December 31, 2021, 2020 and 2019, was $184.3 million, $59.7 million and $10.7 million, respectively. Total cash received upon the exercise of stock options was $20.8 million for the year ended December 31, 2021.

Restricted Stock Units. The following table summarizes restricted stock unit activity and related information under all equity plans for the year ended December 31, 2021:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value Per Share	Weighted Average Remaining Vesting Period	Aggregate Intrinsic Value (in 000s)
Outstanding at December 31, 2020	1,401,732	$ 20.91		
Granted	3,337,716	68.94		
Vested	(451,620)	19.92		
Cancelled	(278,996)	50.39		
Outstanding at December 31, 2021	4,008,832	$ 58.60	3.86	$ 234,557
Restricted stock units expected to vest at December 31, 2021	2,011,455	$ 61.21	2.73	$ 234,557

During the year ended December 31, 2021, 1,997,377 performance-based restricted stock units were granted and are included in the table above, none of which had vested.

As of December 31, 2021, 2020 and 2019, the unrecognized compensation cost related to outstanding restricted stock units (excluding those with unachieved performance-based conditions) was $98.2 million, $20.8 million and $6.2 million, respectively, which was expected to be recognized as expense over approximately 3.2 years, 2.9 years and 2.7 years, respectively.

Stock-Based Compensation Expense

The allocation of stock-based compensation for all stock awards is as follows (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Research and development	$ 35,140	$ 18,636	$ 9,804
General and administrative	19,224	12,117	7,606
Total stock-based compensation expense	$ 54,364	$ 30,753	$ 17,410

Stock Option Grants Valuation. The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee and nonemployee stock option grants were as follows:

	Years Ended December 31,		
	2021	2020	2019
Risk–free interest rate	0.5%	1.0%	2.4%
Expected volatility	76.5%	77.5%	80.1%
Expected term (in years)	5.1	5.5	6.1
Expected dividend yield	0.0%	0.0%	0.0%

Risk-free interest rate. The Company bases the risk-free interest rate assumption on observed interest rates appropriate for the expected term of the stock option grants.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends.

Expected volatility. During the years ended December 31, 2021 and 2020, the Company based the expected volatility on the historical volatility of its common stock over the most recent period commensurate with the estimated expected term of the Company's stock options, as the Company determined there was sufficient operating history and company-specific historical volatility to estimate the expected volatility. During the year ended December 31, 2019, the expected volatility assumption was based on historical volatilities of a peer group of similar companies whose share prices were publicly available. The peer group was developed based on companies in the biotechnology industry.

Expected term. The expected term represents the period of time that options are expected to be outstanding. During the years ended December 31, 2021 and 2020, the Company estimated the expected term using historical experience and anticipated future exercise behavior. During the year ended December 31, 2019, due to limited historical exercise behavior, the Company determined the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance is as follows:

	December 31,	
	2021	2020
Convertible preferred stock (if converted)	13,972,745	13,972,745
Common stock options	7,708,263	10,432,822
Restricted stock units	4,008,832	1,401,732
Awards available under the 2013 Plan	3,356,946	2,618,516
Awards available under the Inducement Plan	856,000	550,000
Employee stock purchase plan	729,000	729,000
Total	30,631,786	29,704,815

10. Income Taxes

The following is a reconciliation of the Company's expected federal income tax provision (benefit) to the actual income tax provision (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Tax computed at federal statutory rate	$ (44,551)	$ (36,411)	$ (20,611)
State tax, net of federal tax benefit	(6,966)	(1,296)	(2,088)
Non-deductible compensation	10,202	75	86
Permanent differences	(686)	(240)	89
Stock compensation	(35,852)	(6,073)	359
R&D tax credits	(12,140)	(7,177)	(7,285)
Reserve for uncertain tax positions	7,192	1,555	2,163
Other	84	70	77
Valuation allowance	82,717	49,497	27,210
Income tax expense	$ —	$ —	$ —

Significant components of the Company's deferred tax assets are summarized as follows (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Section 59e amortization	$ 95,172	$ 48,195
Net operating losses	62,913	41,213
R&D tax credits	35,387	23,488
Intangible asset amortization	6,985	2,615
Deferred revenue	8,706	11,915
Stock compensation	8,710	4,307
Lease liability	24,112	20,433
Other	6,972	10,208
Total deferred tax assets	248,957	162,374
Deferred tax liabilities:		
Depreciation	(7,323)	(4,220)
Right-of-use assets	(14,851)	(14,088)
Total deferred tax liabilities	(22,174)	(18,308)
Net of deferred tax assets and liabilities	226,783	144,066
Valuation allowance	(226,783)	(144,066)
Net deferred tax assets	$ —	$ —

A valuation allowance of $226.8 million and $144.1 million at December 31, 2021 and 2020, respectively, has been established to offset the deferred tax assets, as realization of such assets is uncertain.

At December 31, 2021, the Company had federal and California net operating loss (NOL) carryforwards of $289.7 million and $291.2 million, respectively, which may be available to offset future taxable income. The federal and California NOL carryforwards begin to expire in 2027 and 2028, respectively, unless previously utilized. At December 31, 2021, the Company had federal and California research and development (R&D) credit carryforwards of $25.7 million and $25.8 million, respectively. The federal R&D tax credit carryforwards will begin to expire in 2035 unless previously utilized. The California R&D credit carryforwards will carry forward indefinitely.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, (the Code), substantial changes in our ownership may limit the amount of net operating loss and research and development credit carryforwards that could be used annually in the future to offset taxable income. The tax benefits related to future utilization of federal and state net operating loss carryforwards, credit carryforwards, and other deferred tax assets may be limited or lost if cumulative changes in ownership exceeds 50% within any three-year period. The Company completed a study to assess whether an ownership change, as defined by Section 382 of the Internal Revenue Code of 1986, had occurred from the Company's formation through December 31, 2015. Based upon this study, the Company determined that several ownership changes had occurred. Accordingly, the Company reduced its deferred tax assets related to the federal NOL carryforwards and the federal R&D credit carryforwards that are anticipated to expire unused as a result of these ownership changes. These tax attributes were excluded from deferred tax assets with a corresponding reduction of the valuation allowance with no net effect on income tax expense or the effective tax rate. The Company updated the study through December 31, 2021 and concluded there were no ownership changes during 2021. Future ownership changes may further limit the Company's ability to utilize its remaining tax attributes.

The Company files income tax returns in the United States and California. The Company currently has no years under examination by any jurisdiction; however, the Company is subject to income tax examination by federal and California tax authorities for years beginning in 2018 and 2017, respectively. However, to the extent allowed by law, the taxing authorities may have the right to examine prior periods where NOLs and tax credits were generated and carried forward, and make adjustments up to the amount of the carryforwards.

The change in the Company's unrecognized tax benefits is summarized as follows (in thousands):

	December 31,		
	2021	2020	2019
Beginning unrecognized tax benefits	$ 19,779	$ 16,822	$ 13,547
Increase related to current year tax positions	17,557	1,837	3,196
Increase related to prior year tax positions	—	1,120	79
Decrease related to prior year tax positions	(81)	—	—
Ending unrecognized tax benefits	$ 37,255	$ 19,779	$ 16,822

The Company does not anticipate that the amount of unrecognized tax benefits as of December 31, 2021 will significantly change within the next twelve months. Due to the valuation allowance recorded against the Company's deferred tax assets, none of the total unrecognized tax benefits as of December 31, 2021 would reduce the effective tax rate if recognized. The Company has not recognized interest or penalties related to income tax matters in its consolidated statements of operations and comprehensive loss since inception.

11. Employee Benefits

Effective January 1, 2009, the Company adopted a defined contribution 401(k) plan for employees who are at least 21 years of age. Employees are eligible to participate in the plan beginning on the first day of the calendar quarter following date of hire. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation. The Company makes discretionary contributions to the 401(k) Plan equal to 100 percent of each employee's pretax contributions up to 20 percent of the IRS Standard Limit. No matching contributions have been made by the Company as of December 31, 2021 since the adoption of the 401(k) plan.

12. Commitments and Contingencies

License Agreements

The Company has entered into exclusive license agreements with certain academic institutions and universities pursuant to which the Company acquired certain intellectual property. Pursuant to each agreement, as consideration for an exclusive license to the intellectual property, the Company paid a license fee, reimbursed the institution for historical patent costs and, in certain instances, issued the institution shares of restricted common stock. Additionally, under each agreement, the institution is generally eligible to receive future consideration including, but not limited to, annual maintenance fees, royalties, milestone payments and sublicensing fees. Each of the license agreements is generally cancelable by the Company, given appropriate prior written notice. Minimum annual payments to maintain these cancelable licenses total an aggregate of $0.4 million. See Note 2 of the notes to the consolidated financial statements for additional information on certain licenses.

Litigation

From time to time, the Company may be involved in various lawsuits, legal proceedings, or claims that arise in the ordinary course of business. Management believes there are no claims or actions pending against the Company as of December 31, 2021 which will have, individually or in the aggregate, a material adverse effect on its business, liquidity, financial position, or results of operations. Litigation, however, is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm the Company's business.

13. Subsequent Events

In February 2022, the Company achieved a research milestone associated with a product candidate directed to a second tumor-associated antigen under the Janssen Agreement; the amount due under the milestone is $3.0 million.

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

None.

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure 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 our management, including the individual serving as our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on our management's evaluation (with the participation of our principal executive officer and principal financial officer) of our disclosure controls and procedures as required by Rules 13a-15 and 15d-15 under the Exchange Act, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2021, the end of the period covered by this report.

Management's Report on Internal Control Over Financial Reporting. The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2021, our internal control over financial reporting was effective based on those criteria.

Our independent registered public accounting firm, Ernst & Young LLP, has audited the financial statements included in this Form 10-K and has issued an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2021, as stated in their attestation report, which is included elsewhere herein.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Fate Therapeutics, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Fate Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). In our opinion, Fate Therapeutics, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated February 28, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting 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 effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Diego, California
February 28, 2022

ITEM 9B. Other Information

None.

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

Except as set forth below, the information required by this item is contained in our definitive proxy statement (the Proxy Statement), to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after the conclusion of our fiscal year ended December 31, 2021 and is incorporated in this Annual Report on Form 10-K by reference.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is posted on the Corporate Governance section of our website, which is located at www.fatetherapeutics.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions, or any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

ITEM 11. Executive Compensation

The information required by this item is contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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

The information required by this item is contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 13. Certain Relationships and Related Party Transactions, and Director Independence

The information required by this item is contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 14. Principal Accounting Fees and Services

Our independent public accounting firm is Ernst & Young, LLP, San Diego, CA, PCAOB Auditor ID 42.

The information required by this item is contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this report:

(1) *Index list to Financial Statements:*

(2) *Financial Statement Schedules*

All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

(3) *Exhibits*

The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this report.

ITEM 16. Form 10-K Summary

None.

EXHIBIT INDEX

Exhibit Number	Exhibit Title	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant	S-1/A	333-190608	3.2	August 29, 2013
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect	8-K	001-36076	3.1	June 7, 2021
3.3	Certificate of Designation of Preferences, Rights and Limitations of Class A Convertible Preferred Stock	8-K	001-36076	3.1	November 29, 2016
3.4	Amended and Restated Bylaws of the Registrant, as currently in effect	10-K	001-36076	3.3	February 24, 2021
4.1	Specimen Common Stock Certificate	S-1/A	333-190608	4.1	August 29, 2013
4.2	Description of Securities	10-K	001-36076	4.5	February 24, 2021
4.3	Form of Pre-Funded Warrant	8-K	001-36076	4.1	January 8, 2021
10.1#	2007 Equity Incentive Plan and forms of agreements thereunder	S-1/A	333-190608	10.1	August 29, 2013
10.2#	Amended and Restated 2013 Stock Option and Incentive Plan and forms of agreements thereunder	10-K	001-36076	10.2	February 24, 2021
10.3#	Form of Unrestricted Stock Award Agreement under the 2013 Stock Option and Incentive Plan	8-K	001-36076	10.2	January 7, 2015
10.4#	2013 Employee Stock Purchase Plan	S-1/A	333-190608	10.24	September 16, 2013
10.5#	Amended and Restated Employment Agreement by and between the Registrant and Scott Wolchko, dated January 14, 2018	10-K	001-36076	10.5	March 5, 2018
10.6#	Amended and Restated Senior Executive Incentive Bonus Plan	8-K	001-36076	10.1	January 7, 2015
10.7#	Amended and Restated Non-Employee Director Compensation Policy	10-Q	001-36076	10.1	August 4, 2021
10.8#	Fate Therapeutics, Inc. Amended and Restated Inducement Equity Plan	10-K	001-36076	10.8	February 24, 2021
10.9#	Forms of Stock Option Agreement under Fate Therapeutics, Inc. Inducement Equity Plan	10-K	001-36076	10.9	February 24, 2021
10.10#	Forms of Restricted Stock Unit Award Agreement under Fate Therapeutics, Inc. Inducement Equity Plan	10-K	001-36076	10.10	February 24, 2021
10.11	Lease Agreement by and between the Registrant and ARE-3535/3565 General Atomics Court, LLC, dated December 3, 2009	S-1	333-190608	10.14	August 13, 2013
10.12	First Amendment to Lease Agreement by and between the Registrant and ARE-3535/3565 General Atomics Court, LLC, dated October 1, 2011	S-1	333-190608	10.15	August 13, 2013
10.13	Second Amendment to Lease Agreement by and between the Registrant and ARE-3535/3565 General Atomics Court, dated September 26, 2013	S-1/A	333-190608	10.25	September 30, 2013
10.14	Third Amendment to Lease Agreement by and between the Registrant and ARE-3535/3565 General Atomics Court, dated September 2, 2014	10-K	001-36076	10.15	March 3, 2016

10.15	Fourth Amendment to Lease Agreement by and between the Registrant and ARE-3535/3565 General Atomics Court, dated March 2, 2015	10-K	001-36076	10.16	March 3, 2016
10.16	Fifth Amendment to Lease Agreement by and between the Registrant and ARE-3535/3565 General Atomics Court, dated June 1, 2016	10-Q	001-36076	10.2	August 8, 2016
10.17	Form of Indemnification Agreement	S-1/A	333-190608	10.20	August 29, 2013
10.18†	Whitehead Institute for Biomedical Research Exclusive Patent License Agreement between the Registrant and the Whitehead Institute for Biomedical Research, dated as of February 24, 2009	10-K	001-36076	10.19	February 24, 2021
10.19†	License Agreement between the Registrant and The Scripps Research Institute, dated as of July 13, 2009	10-K	001-36076	10.20	February 24, 2021
10.20†	License Agreement between the Registrant and The Scripps Research Institute, dated as of May 25, 2010	10-K	001-36076	10.21	February 24, 2021
10.21†	License Agreement between the Registrant and The Scripps Research Institute, dated as of August 24, 2010	10-K	001-36076	10.22	February 24, 2021
10.22	Securities Purchase Agreement, dated August 6, 2016, by and among the Registrant and the Purchasers	8-K	001-36076	10.1	August 8, 2016
10.23	Registration Rights Agreement, dated August 6, 2016, by and among the Registrant and the Purchasers	8-K	001-36076	10.2	August 8, 2016
10.24	Securities Purchase Agreement, dated November 21, 2016, by and among the Registrant and the Purchasers	8-K	001-36076	10.1	November 22, 2016
10.25	Registration Rights Agreement, dated November 21, 2016, by and among the Registrant and the Purchasers	8-K	001-36076	10.2	November 22, 2016
10.26#	Severance and Change in Control Policy	10-K	001-36076	10.32	March 5, 2018
10.27#	Offer Letter by and between the Registrant and Cindy R. Tahl, dated October 23, 2009	10-K	001-36076	10.33	March 5, 2019

10.28	Sixth Amendment to the Lease Agreement by and between the Registrant and ARE-3535/3565 General Atomics Court, dated May 31, 2018	10-Q	001-36076	10.1	August 6, 2018
10.29	Amended and Restated Exclusive License Agreement by and between the Registrant and Memorial Sloan Kettering Cancer Center, dated May 15, 2018	10-Q	001-36076	10.2	August 6, 2018
10.30†	Exclusive License Agreement by and between the Registrant and The David Gladstone Institutes, dated September 11, 2018	10-Q	001-36076	10.1	November 1, 2018
10.31†	Collaboration and Option Agreement by and between the Registrant and Ono Pharmaceutical Co., Ltd., dated September 14, 2018	10-Q/A	001-36076	10.2	February 8, 2019
10.32#	Offer Letter by and between the Registrant and Bahram Valamehr, dated November 23, 2009	10-K	001-36076	10.38	March 5, 2019
10.33†	Lease Agreement by and between the Registrant and Scripps Summit Investments LLC, dated January 7, 2020	10-K	001-36076	10.34	March 2, 2020
10.34†	Collaboration and Option Agreement by and between the Registrant and Janssen Biotech, Inc., dated April 2, 2020	10-Q	001-36076	10.1	August 5, 2020
10.35†	Stock Purchase Agreement by and between the Registrant and Johnson & Johnson Innovation – JJDC, Inc., dated April 2, 2020	10-Q	001-36076	10.2	August 5, 2020
10.36†	Stock Purchase Agreement by and between the Registrant and Johnson & Johnson Innovation – JJDC, Inc., dated June 8, 2020	10-Q	001-36076	10.3	August 5, 2020
10.37#	Offer Letter by and between the Registrant and Edward Dulac III, dated May 20, 2020	8-K	001-36076	10.1	August 19, 2020
10.38†	Letter Agreement, dated December 4, 2020, by and between the Registrant and Ono Pharmaceutical Co., Ltd.	10-K	001-36076	10.39	February 24, 2021
10.39†	Patent License Agreement by and between the Registrant and Max-Delbrück-Centrum für Molekulare Medizin in der Helmholtz-Gemeinschaft, dated August 30, 2019	10-K	001-36076	10.40	February 24, 2021
10.40†	License Agreement, dated April 9, 2020, by and between the Registrant and Dana-Farber Cancer Institute, Inc.	—	—	—	Filed herewith
14.1	Amended Code of Business Conduct and Ethics	10-K	001-36076	14.1	March 5, 2019
21.1	Subsidiaries of the Registrant	10-K	001-36076	21.1	March 5, 2019
23.1	Consent of Independent Registered Public Accounting Firm	—	—	—	Filed herewith
24.1	Power of Attorney (included on signature page to this Annual Report)	—	—	—	Filed herewith

31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14 and 15-d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14 and 15-d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	—	—	—	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	—	—	—	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	—	—	—	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	Filed herewith
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).	—	—	—	Filed herewith

† Certain provisions of this Exhibit have been omitted as confidential information.
# Indicates a management contract or any compensatory plan, contract or arrangement.

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.

Fate Therapeutics, Inc.

Date: February 28, 2022

By: /s/ J. Scott Wolchko
J. Scott Wolchko
President and Chief Executive Officer
(Principal Executive Officer and Authorized Signatory)

Date: February 28, 2022

By: /s/ Edward J. Dulac III
Edward J. Dulac III
Chief Financial Officer
(Principal Financial and Accounting Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of J. Scott Wolchko and Edward J. Dulac III as his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated:

SIGNATURE	TITLE	DATE
/s/ J. Scott Wolchko J. Scott Wolchko	President and Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2022
/s/ Edward J. Dulac III Edward J. Dulac III	Chief Financial Officer (Principal Financial and Accounting Officer)	February 28, 2022
/s/ William H. Rastetter William H. Rastetter, Ph.D.	Chairman of the Board and Director	February 28, 2022
/s/ John D. Mendlein John D. Mendlein, Ph.D., J.D.	Vice Chairman of the Board and Director	February 28, 2022
/s/ Shefali Agarwal Shefali Agarwal, M.D.	Director	February 28, 2022
/s/ Timothy P. Coughlin Timothy P. Coughlin	Director	February 28, 2022
/s/ Robert S. Epstein Robert S. Epstein	Director	February 28, 2022
/s/ Robert Hershberg Robert Hershberg, M.D., Ph.D.	Director	February 28, 2022
/s/ Karin Jooss Karin Jooss, Ph.D.	Director	February 28, 2022
/s/ Michael Lee Michael Lee	Director	February 28, 2022
/s/ Yuan Xu Yuan Xu, Ph.D.	Director	February 28, 2022

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE OF INFORMATION THAT THE REGISTRANT CUSTOMARILY AND ACTUALLY TREATS AS PRIVATE AND CONFIDENTIAL. SUCH EXCLUDED INFORMATION HAS BEEN MARKED WITH "[***]".

CONFIDENTIAL DFCI AGREEMENT NO. [***]

LICENSE AGREEMENT

Title of Agreement: MICA/B Exclusive License Agreement

Effective Date: April 9, 2020

Parties: Licensor

Dana-Farber Cancer Institute, Inc.
450 Brookline Ave.
Boston, MA 02215

Licensee

Fate Therapeutics, Inc.
3535 General Atomics Court, Suite 200
San Diego, CA 92121

DFCI Agreement No.: [***]

LICENSE AGREEMENT

This Exclusive License Agreement, effective as of April 9, 2020 ("Effective Date"), is between the Dana-Farber Cancer Institute, Inc., a Massachusetts non-profit organization having a principal place of business at 450 Brookline Ave., Boston, MA 02215 ("DFCI") and Fate Therapeutics, Inc., a Delaware corporation having a principal place of business at 3535 General Atomics Court, Suite 200, San Diego, CA 92121 ("Licensee"). Each of DFCI and Licensee may be referred to herein as a "Party" or collectively as the "Parties."

Background

WHEREAS, the Inventors, as later defined, have reported certain inventions to DFCI, identified as DFCI case number [***], "Compositions and Methods for Inhibition of [***] Shedding".

WHEREAS, DFCI desires to promote the public interest by granting a license to the Patent Rights as later defined;

WHEREAS, Licensee has represented to DFCI that it has the capabilities and/or experience to develop, produce, market and sell products utilizing technology that is similar to the technology that is the subject of this Agreement and has the financial capacity and the strategic commitment to facilitate the transfer of the technology for the public interest; and

WHEREAS, Licensee desires to obtain a license to DFCI's rights and DFCI is willing to grant a license upon the terms and conditions of this Agreement.

NOW, THEREFORE, DFCI and Licensee therefore agree as follows.

1. – DEFINITIONS

The following terms set forth in this ARTICLE I have the meanings set forth below:

a. "Affiliate" means any Person that is controlled by, controlling, or under common control with Licensee. For this purpose "control" means either (a) direct or indirect beneficial ownership of at least fifty percent (50%) interest in the voting stock (or the equivalent) of the relevant entity, (b) having the right to direct, appoint or remove a majority of members of such entity's board of directors (or their equivalents) or (c) having the power to control the general management of such entity, in each case whether by law or contract.

b. "Agreement" means this License Agreement, including all attached schedules.

c. "Applicable Law" means any national, international, supra-national, federal, state or local laws, treaties, statutes, ordinances, rulings, rules and regulations, including any rules, regulations, guidance or guidelines, or requirements of any regulatory authorities, national securities exchanges or securities listing organizations, governmental authorities, courts, tribunals, agencies, legislative bodies and commissions that are in effect from time to time during the Term and applicable to a particular activity hereunder.

d. "Calendar Quarter" means a period of three (3) consecutive months corresponding to the calendar quarters commencing on the first day of January, April, July or October, or any partial period thereof immediately following the Effective Date or immediately prior to the termination or expiration of this Agreement.

e. "Calendar Year" means a period of twelve (12) consecutive months corresponding to the calendar year commencing on the first day of January, or any partial period thereof immediately following the Effective Date or immediately prior to the termination or expiration of this Agreement.

f. "Change of Control" means (i) a merger or consolidation of Licensee in which Licensee's shareholders immediately prior to such transaction hold less than fifty percent (50%) of the securities or other ownership or voting interests representing the equity of the surviving entity immediately after such transaction, (ii) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of Licensee, or (iii) the sale or other transfer to a Third Party of all or substantially all of Licensee's assets.

g. "Clinical Study" means any clinical trial in humans, including any Phase 1 Clinical Study, Phase 2 Clinical Study or Phase 3 Clinical Study.

h. "Combination" shall have the meaning set forth in Section 1.25.

i. "Confidential Information" means all proprietary or confidential information or material in tangible form disclosed hereunder, or proprietary or confidential information otherwise disclosed in non-tangible form hereunder; including business, sales, and financial information, product development and business plans, electronic data and other proprietary information, samples, compounds, methods, formulas, processes, protocols, technologies and equipment employed, information relating to quality assurance, procedures for and record keeping, techniques, inventions, apparatus, and formulae, relating to a Party's current, future and proposed compounds, compositions, and biological materials.

j. "Competitive Infringement" shall have the meaning set forth in Section 7.2(b).

k. "Control" or "Controlled" means, with respect to any Patent Rights or other intellectual property right, possession of the right to grant a license, sublicense or other right to or under such patent or other intellectual property right as provided for herein without (i) violating the terms of any agreement or other arrangement with any Third Party, (ii) incurring any payment obligation to a Third Party, and (iii) violating any Applicable Law.

l. "Cover" means, with respect to a given product, process, method or service, that a Valid Claim (and in the event such Valid Claim is contained in a pending patent, assuming such patent is issued) would, absent a license thereunder, be infringed by the research, development, making, using, sale, offering for sale, importation or other exploitation of such product, process, method or service.

m. "Development Plan" shall have the meaning set forth in Section 5.1(b).

n. "Diligence Benchmarks" shall have the meaning set forth in Section 5.1(c).

o. "Distributor" means any Third Party that purchases its requirements for Royalty Bearing Product in final packaged form from Licensee or its Affiliates or Sublicensees and is appointed as a Distributor to distribute, market and resell such Royalty Bearing Product in a country; provided that a Third Party that pays Licensee, or an Affiliate or Sublicensee, a royalty or similar payment based on the sale or transfer by such Third Party of Royalty Bearing Product shall be a Sublicensee, and not a Distributor, for purposes of this Agreement.

p. "Field of Use" means Field of Use 1 and Field of Use 2.

q. "Field of Use 1" means cellular therapeutics for the treatment of human disease.

r. "Field of Use 2" means iPSC-derived cellular therapeutics for the treatment of human disease.

s. "First Commercial Sale" means the initial transfer of Royalty Bearing Product by or on behalf of Licensee, an Affiliate or Sublicensee which results in Net Sales.

t. "Future Patent Expenses" shall have the meaning set forth in Section 3.1(b).

u. "Indemnitees" shall have the meaning set forth in Section 9.1.

v. "Inventors" means Lucas Ferrari De Andrade and Kai W. Wucherpfennig.

w. "Licensed Process" means any process, method or service the use, performance, sale or offer for sale of which (or a part thereof) is Covered by a Valid Claim.

x. "Licensed Product" means any product (a) the making, using, selling, offering for sale or importing of which product (or part thereof) is Covered by a Valid Claim, or (b) that is made, used or sold through performance of a Licensed Process.

y. "Net Sales" means:

i. the gross income billed or invoiced (or, if greater or not otherwise billed or invoiced, the gross amount received) by Licensee, its Affiliates or Sublicensees from the sale or transfer of a Royalty Bearing Product or a service performed using a Royalty Bearing Product to Third Parties (including Distributors and end users) less the following deductions to the extent such deductions (i) are appropriately allocated to the Royalty Bearing Product, (ii) do not exceed [***] amounts in the country in which the transaction occurs and (iii) are consistent with the accounting standards of the selling Person:

1. Outbound transportation charges or allowances actually paid or granted;

2. Trade, quantity or cash discounts, if any, to the extent actually allowed and taken;

3. Credits or allowances made or given due to rejects, returns, or retroactive price reductions for any amount not collected that are specifically identifiable to Royalty Bearing Products;

4. Any tax or governmental charge directly on the sale or transportation, use or delivery of Royalty Bearing Products paid by Licensee, its Affiliate or Sublicensee that is reflected on a document of sale and not recovered from the purchaser.

ii. In the case of a sale or other transfer of a Royalty Bearing Product within Licensee or between or among Licensee, a Sublicensee or their Affiliates for further sale or other transfer by such transferee, Net Sales shall be based on the gross amount billed, invoiced, or received (as applicable) for the first sale or other transfer of such Royalty Bearing Product to (i) an entity other than Licensee, a Sublicensee or their Affiliates, or (ii) a transferee that is the final purchaser or transferee.

iii. No deductions will be made for commissions paid to individuals whether they are with independent sales agencies or regularly employed by Licensee, its Affiliates or Sublicensees, and on its payroll, or for cost of collections.

iv. Neither Licensee nor an Affiliate or Sublicensee of Licensee shall accept non-monetary consideration for any Royalty Bearing Product or any service performed using any Royalty Bearing Product without the prior written consent of DFCI.

v. If a Royalty Bearing Product or a service performed using any Royalty Bearing Product is billed, invoiced or otherwise transferred at a discounted price that is substantially lower than the customary prices charged by Licensee, its Affiliate or Sublicensee, or billed, invoiced, or in accordance with the preceding paragraph or otherwise transferred for non-monetary consideration (whether or not at a discount), Net Sales will be calculated based on the average non-discounted amount charged for the Royalty Bearing Product or such service in an arms-length transaction to an independent Third Party during the same Calendar Quarter in the same country or, in the absence of such sales, on the fair market value of the Royalty Bearing Product or such service at the time of the transaction assuming an arm's length transaction made in the ordinary course of business.

vi. Notwithstanding the foregoing, transfers or dispositions of Royalty Bearing Product:

1. in connection with patient assistance programs,

2. for charitable or promotional purposes, or

3. for preclinical, clinical, regulatory or regulatory purposes or under so-called "named patient" or other limited access programs,

shall not, in any such case, result in Net Sales or constitute a First Commercial Sale of such Royalty Bearing Product if Licensee, its Affiliates or Sublicensees do not receive compensation for such transfers or dispositions in excess of Licensee's, its Affiliates' or Sublicensees' cost for such Royalty Bearing Product.

vii. Net Sales shall be deemed to occur on the earlier of the date of billing, invoicing or receiving consideration for a Royalty Bearing Product or a service performed using any Royalty Bearing Product.

viii. If Licensee or its Affiliate or Sublicensee sells a Royalty Bearing Product in combination (in the same package, including as a co-formulation) with one or more other active ingredients that do not constitute Royalty Bearing Products (a "Combination") in a country during a Calendar Quarter, Net Sales of such Royalty Bearing Product in such country during such quarter for the purpose of determining royalties due hereunder shall be determined by multiplying the actual Net Sales of the Combination calculated pursuant to the preceding provisions of this section by a fraction which the Parties determine in good faith fairly represents the value of the Royalty Bearing Product relative to the Combination; provided that in the event the Parties do not agree on such relative value contributions, the Parties shall refer the matter to an independent expert, to be selected by mutual agreement of the Parties, for final determination of such relative value contributions, and such determination will be final and binding upon the Parties, and the costs of such independent expert shall be shared equally by the Parties. For clarity, a "Combination" does not cover any combination therapy or treatment regimen that includes a Royalty Bearing Product and another product that does not constitute a Royalty Bearing Product if such Royalty Bearing Product and such other product are not sold in the same package or as part of the same formulation.

z. "Past Patent Expenses" shall have the meaning set forth in Section 3.1(a).

aa. "Patent Challenge" shall mean any challenge to the validity, patentability, enforceability or non-infringement of any of the Patent Rights or otherwise opposing any of the Patent Rights through a legal or administrative proceeding.

bb. "Patent Rights" means (a) United States provisional patent application and Patent Cooperation Treaty applications described in Schedule 1, (b) any conversion, continuation (or the claims of any continuation-in-part that are entitled to the priority of the applications in (a)), division, or substitution thereon, (c) any patents issuing on the patent applications described in clauses (a) and (b) of this Section 1.28 and (d) any reissues, reexaminations or extensions of such patents, and (e) any foreign counterparts of the patent applications and patents described in clauses (a) through (d) of this Section 1.28 (provided that if the patents referred to in (c)-(e) are continuation-in-part, then only to the claims entitled to priority of the applications in (a)).

cc. "Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization.

dd. "Phase 1 Clinical Study" means a clinical trial that generally provides for the first introduction into humans of a pharmaceutical or biologic product with the primary purpose of determining feasibility,

safety, metabolism, and pharmacokinetic properties and clinical pharmacology, including dose ranging, of such product, in a manner that is generally consistent with 21 C.F.R. § 312.21(a), as amended (or its successor regulation), or, with respect to any other country or jurisdiction, the equivalent of such a clinical trial in such other country or jurisdiction.

ee. "Phase 2 Clinical Study" means a clinical trial that is intended to explore the effectiveness of a pharmaceutical or biologic product, that is prospectively designed to generate sufficient data (if successful) to commence a Phase 3 Clinical Study of such product, in a manner that is generally consistent with 21 C.F.R. § 312.21(b), as amended (or its successor regulation), or, with respect to any other country or jurisdiction, the equivalent of such a clinical trial in such other country or jurisdiction.

ff. "Phase 3 Clinical Study" means a clinical trial in humans performed to gain evidence with statistical significance of the efficacy of a pharmaceutical or biologic product in a target population, and to obtain expanded evidence of safety for such product that is needed to evaluate the overall benefit-risk relationship of such product, to form the basis for approval of a marketing authorization application by a regulatory authority and to provide an adequate basis for physician labeling, in a manner that is generally consistent with 21 C.F.R. § 312.21(c), as amended (or its successor regulation), or, with respect to any other country or jurisdiction, the equivalent of such a clinical trial in such other country or jurisdiction.

gg. "Regulatory Exclusivity" means any exclusive marketing rights or data exclusivity rights conferred by any regulatory authority with respect to a Royalty Bearing Product in a country or jurisdiction in the Territory, other than a patent, including exclusivity for an approved New Drug Application (as defined in the FFDCA) or any corresponding foreign application in the Territory, new chemical entity exclusivity, new clinical data exclusivity, orphan drug exclusivity, pediatric exclusivity, or rights similar thereto in other countries or regulatory jurisdictions.

hh. "Royalty Bearing Product" means any Licensed Product or Licensed Process.

ii. "Royalty Term" means, on a Royalty Bearing Product-by-Royalty Bearing Product and country-by-country basis, the period of time commencing with the First Commercial Sale of a Royalty Bearing Product in a country and continuing until the expiration or termination of the last to expire Valid Claim of a Patent Right Covering such Royalty Bearing Product in such country.

jj. "Sublicense" means an agreement in which Licensee (a) grants or otherwise transfers any of the rights licensed to Licensee hereunder for the purpose of designing, developing, testing, making, using, selling, performing or practicing of Royalty Bearing Products or use or practice of Patent Rights, (b) agrees not to assert such rights or to sue, prevent or seek a legal remedy for the performance or practice of same, or (c) is under an obligation to grant, assign or otherwise transfer any such rights or non-assertion, or to forebear from granting or otherwise transferring such rights to any other entity. Agreements expressly considered Sublicenses include licenses, option agreements, "lock up" agreements, right of first refusal agreements, non-assertion agreements, and covenants not to sue. Notwithstanding the foregoing, an agreement by Licensee, its Affiliate, or Sublicensee granting rights under this Agreement to a Third Party Partner shall not be considered a Sublicense of rights under this Agreement.

kk. "Sublicense Income" means consideration in any form other than running royalties on Net Sales that Licensee or an Affiliate receives from a Sublicensee or its Affiliates in connection with a Sublicense of the Patent Rights. Sublicense Income shall include any upfront payments, license or option fees, lump sum payment, equity securities, milestone payments and other payments. In the event Licensee or any of its Affiliates receives non-cash consideration in connection with a Sublicense, Sublicense Income shall be calculated based on the fair market value of such consideration at the time of the transaction, assuming an arm's length transaction made in the ordinary course of business. Sublicense Income shall exclude [***]. Licensee will not structure agreements in a single or multiple transaction to minimize Sublicense Income. Where payment to Licensee in connection with a Sublicense of the

Patent Rights includes payment for other licenses or rights granted by Licensee, the sublicense revenue shall be reasonably apportioned between the payment considered Sublicense Income and the payment for other licenses or grants not considered Sublicense Income under this License, and shall be agreed upon by the Parties in good faith. If the Parties are unable to reach agreement on this apportionment, the Parties will resolve the dispute per Section XII but in no circumstance will the Sublicense payments owed to DFCI be reduced by more than [***] of what would have been owed absent any allocation.

ll. "Sublicensee" means a Third Party to which Licensee has, directly or indirectly, granted a Sublicense of the rights granted to Licensee hereunder.

mm. "Taxes" shall have the meaning set forth in Section 4.3(b).

nn. "Term" shall have the meaning set forth in Section 8.1.

oo. "Territory" means worldwide.

pp. "Third Party" means any Person other than DFCI, Licensee or any of their respective Affiliates.

qq. "Third Party License" shall have the meaning set forth in Section 3.1(g).

rr. "Third Party Partner" means a Third Party, such as a contract research organization, contract manufacturing organization and/or distributor, that will be sharing certain rights under this Agreement so that such Third Party may exercise such rights on behalf of Licensee pursuant to a written agreement between Licensee and such Third Party.

ss. "Valid Claim" means (a) a claim in an issued and unexpired patent included in the Patent Rights that: (i) has not been permanently revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, and is not subject to appeal, (ii) has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise and (iii) has not been lost through an interference, reexamination or reissue proceeding, and is not subject to appeal, or (b) a pending claim of a pending patent application included in the Patent Rights which has not been finally rejected or disallowed by an administrative agency action from which no appeal can be taken, and which has not been pending for more than [***] years from the first substantive office action. The invalidity of a particular claim in one or more countries shall not invalidate such claim in any remaining countries. For the avoidance of doubt, a pending claim of a patent application filed pursuant to the Patent Cooperation Treaty shall be considered pending in all designated jurisdictions.

2. – GRANT OF LICENSES, RESERVED RIGHTS AND SUBLICENSING

a. License Grants.

i. Subject to all of the terms and conditions of this Agreement (including without limitation the non-exclusive license granted to the United States government in Section 2.4 and the non-exclusive rights granted to a Third Party under the license dated December 23, 2013, DFCI grants to Licensee an exclusive, royalty-bearing license under Patent Rights limited only to the [***], with the right to grant Sublicenses in accordance with Section 2.5, to use, have used, make, have made, offer to sell, sell and import Royalty Bearing Products in the Territory for the Field of Use 2 during the Term.

ii. Subject to all of the terms and conditions of this Agreement (including without limitation the non-exclusive license granted to the United States government in Section 2.4), DFCI grants to Licensee a non-exclusive, royalty-bearing license under Patent Rights limited only to the [***], with the right to grant Sublicenses in accordance with Section 2.5, to use, have used, make, have made, offer to sell, sell and import Royalty Bearing Products in the Territory for the Field of Use 1 during the Term.

b. **Affiliates/Third Party Partners**. Licensee has the right to have some or all of its rights or obligations under this Agreement exercised or performed on Licensee's behalf by one or more of its Affiliates and/or a Third Party Partner, such exercise or performance to be consistent with all of the terms and conditions of this Agreement. If an Affiliate and/or Third Party Partner of Licensee does assume any of Licensee's obligations under the Agreement, Licensee guarantees performance by the Affiliate and/or Third Party Partner of such obligation. Any act or omission of an Affiliate and/or Third Party Partner which would be a breach of this Agreement if performed by Licensee shall be deemed to be a breach by Licensee of this Agreement. Notwithstanding anything to the contrary in this Agreement, in no event shall an Affiliate of Licensee have the right to grant a sublicense of any rights licensed to Licensee under this Agreement.

c. **No Implied Licenses.** This Agreement confers no license or rights by implication, estoppel or otherwise under any other technology, patent applications or patents owned, licensed or otherwise controlled in whole or in part by DFCI other than the licensed Patent Rights as set forth in this Agreement.

d. **Reserved Rights.** Notwithstanding anything to the contrary in this Agreement, the licenses granted by DFCI under this Agreement are subject to the following reserved rights:

i. The rights of the United States of America, as set forth in (i) Public laws 96-517 and 98-620, the regulations promulgated thereunder and any successor statutes and regulations, in each case as amended from time to time and (ii) the policy of any funding agencies. Any rights granted hereunder which are greater than permitted by the rights reserved by the United States of America detailed in the preceding sentence are subject to modification as required to conform to such rights reserved.

ii. DFCI's right to grant non-exclusive, non-transferable licenses under Patent Rights to (i) other academic, government or non-profit institutions in the Field of Use for non-commercial purposes, including research, teaching and education purposes and (ii) Third Parties to make or sell research reagents or other research tools solely for research use only, where research use expressly excludes use in the making, manufacture, IND-enabling studies, clinical development and/or commercialization of a human therapeutic.

iii. DFCI's right to use the licensed Patent Rights in the Territory for the Field of Use for non-commercial purposes, including without limitation research, teaching, and education purposes.

e. **Sublicensing**.

i. **General.** Licensee has the right to grant Sublicenses under this Agreement in accordance with and subject to the terms and conditions of this Agreement; provided that any Sublicense by Licensee of the rights granted under Section 2.1(b) must be accompanied by a Sublicense of the rights granted to Licensee under Section 2.1(a)**.** Notwithstanding anything to the contrary in this Agreement, it is expressly understood that Licensee shall not grant a Sublicense to any entity engaged in the sales of tobacco or tobacco-related products. Licensee remains responsible for the operations of any Sublicensee under a Sublicense, as if the operations were carried out by Licensee under this Agreement. Notwithstanding any Sublicense, Licensee shall remain primarily liable to DFCI for all of Licensee's duties and obligations contained in this Agreement, and any act or omission of a Sublicensee which would be a breach of this Agreement if performed by Licensee shall be deemed to be a breach by Licensee of this Agreement. If DFCI has a claim arising under this Agreement against a Sublicensee, then DFCI may seek a remedy directly against Licensee and may, but is not required to, seek a remedy against the Sublicensee. If a Sublicensee (or an Affiliate of such Sublicensee) undertakes a Patent Challenge of any such Patent Right under which such Sublicensee is sublicensed, then Licensee, upon receipt of notice from DFCI of such Patent Challenge, will terminate the applicable Sublicense.

ii. **Notice and Approval**. Licensee shall promptly notify DFCI in writing of the identity of any Sublicensee.

iii. **Form and Content of Sublicenses.** Licensee shall issue any Sublicense(s) granted by it under this Agreement in writing. Licensee shall include the equivalent of at least the following provisions in all Sublicenses:

1. Sublicensee shall use its [***] efforts to bring the subject matter of the Sublicense into commercial use as quickly as possible and shall report at least annually to Licensee on such efforts and its operations under the Sublicense;

2. DFCI shall be an intended third party beneficiary under the Sublicense with the right to enforce the applicable terms of the Sublicense, including intellectual property ownership and enforcement, indemnification obligations, insurance and compliance with laws, and termination provisions;

3. Sublicensee shall indemnify, defend and hold the Indemnitees harmless to at least the extent that Licensee is obligated to indemnify the Indemnitees under Section 9.1 of this Agreement;

4. Sublicensee shall make payments due to Licensee in relation to Net Sales of Royalty Bearing Products in a timely manner, so that Licensee may comply with its obligations to make payments to DFCI as set forth in ARTICLE III and ARTICLE IV of this Agreement;

5. If Sublicensee undertakes a Patent Challenge with respect to any Patent Rights under which the Sublicensee is sublicensed, then Licensee will be permitted to terminate such sublicense agreement;

6. Sublicensee will comply with the applicable terms and conditions of this Agreement, including Section 2.4 (Reserved Rights), Sections 4.2(a) (Books and Records) and 4.2(b) (Inspections), Sections 5.2 – 5.5 (U.S. Manufacture, Other Government Laws, Patent Marking, and Publicity, respectively), ARTICLE VI (Patent Preparation, Filing, Prosecution and Maintenance), ARTICLE VII (Patent Infringement and Enforcement), Section 8.4(f) (Termination-Sublicenses) and ARTICLE IX (Indemnification, Defense and Insurance), ARTICLE X (Disclaimer of Warranties) and ARTICLE XII (Dispute Resolution).

7. Sublicensees do not have the right to grant further sublicenses.

iv. **Copies of Sublicenses to DFCI.** Licensee shall forward to DFCI an unredacted copy of any and all fully executed Sublicenses within [***] days of the execution of the Sublicense. Licensee shall also forward to DFCI [***] a copy of any reports received by Licensee from its Sublicensee during the [***] under a Sublicense that relate to (1) the Sublicensee's operations under the Sublicense and (2) a royalty or Sublicense Income accounting under the Sublicense. All such Sublicenses provided to DFCI shall be deemed Confidential Information of Licensee.

v. **Licensee's Continuing Obligations.** Nothing in this Section 2.5 may be construed to relieve Licensee of its obligations to DFCI under this Agreement, including but not limited to Licensee's obligations under ARTICLE IX.

vi. **Failure to Comply**. If (A) Licensee grants a Sublicense without notifying DFCI pursuant to Section 2.5(b) or (B) Licensee grants a Sublicense on terms that are inconsistent with the material terms required of Sublicenses pursuant to this Agreement, then such failure will be deemed to be a material breach of this Agreement.

3. – CONSIDERATION

a. **Reimbursements and Other Financial Consideration.** In partial consideration of the rights granted by DFCI to Licensee under this Agreement, Licensee shall make the following payments to DFCI according to this ARTICLE III and ARTICLE IV, on behalf of itself, any Affiliate(s) or Sublicensee(s).

i. **Past Patent Expenses**. Within [***] days after the Effective Date, Licensee shall reimburse DFCI for all [***]; if there are other licensees of the Patent Rights, then Licensee will be only be responsible for [***] of any such costs (the "Past Patent Expenses"). Licensee acknowledges that as of the Effective Date the total amount of these patent expenses is [***].

ii. **Future Patent Expenses.** Licensee shall reimburse [***]; if there are other licensees of the Patent Rights, then Licensee will only be responsible for [***] of any such costs (the "Future Patent Expenses"). Licensee shall pay DFCI within [***] days after DFCI mails Licensee an invoice that documents the out-of-pocket expenses incurred or paid by DFCI during the period being invoiced and states the total amount owed to DFCI.

iii. **Initial License Fee**. Licensee shall pay to DFCI a non-creditable, non-refundable license issue fee in the sum of [***], which is due and payable to DFCI within [***] days [***].

iv. **License Maintenance Fees.** Licensee shall pay DFCI a non-creditable, non-refundable license maintenance fee of [***]. License maintenance fees shall cease to be due [***].

v. **Milestone Payments.** Licensee shall make the following non-creditable (except as set forth in Section 3.1(f), non-refundable milestone payments to DFCI as set forth below. With respect to each Royalty Bearing Product, Licensee shall make the following non-creditable, non-refundable milestone payments to DFCI within [***] days of the occurrence of the following events, whether Licensee, an Affiliate or Sublicensee achieves the events.

1. Developmental Milestones

With respect to each Royalty Bearing Product, Licensee shall make the following non-creditable, non-refundable developmental milestone payments to DFCI within [***] days of the occurrence of the following events, whether Licensee, an Affiliate, Sublicensee, a permitted assignee, or a successor achieves the events. For the avoidance of doubt, all development milestone payments are payable [***].

Development Milestones for each Royalty Bearing Product	
Development Milestone Event	*Development Milestone Payment*
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]

2. Commercialization Milestones

With respect to each Royalty Bearing Product, Licensee shall make the following non-creditable, non-refundable commercialization milestone payments to DFCI within [***] days of the occurrence of the following events, whether Licensee, an Affiliate, Sublicensee,

a permitted assignee, or a successor achieves the events. For the avoidance of doubt, all commercialization milestone payments are payable [***].

Commercialization Milestones for each Royalty Bearing Product	
Commercialization Milestone Event	*Commercialization Milestone Payment*
[***]	$[***]
[***]	$[***]
[***]	$[***]

3. Sales Milestones

With respect to each Royalty Bearing Product in the Field of Use in the Territory, Licensee will make the following non-creditable, non-refundable sales milestone payments to DFCI within [***] days [***], regardless of whether [***]. Each sales milestone payment will be made whether the [***]. For the avoidance of doubt, all sales milestone payments are non-refundable and non-creditable, and payable [***].

Sales Milestones for each Royalty Bearing Product	
Sales Milestone Event	*Sales Milestone Payment*
[***]	$[***]
[***]	$[***]
[***]	$[***]

vi. **Minimum Royalties.** Beginning in [***], Licensee shall pay to DFCI a non-refundable minimum annual royalty in the sum of [***]. Licensee shall pay the [***] to DFCI on or before the [***] and may credit the [***] against any running royalties subsequently due to DFCI under Section 3.1(g) [***].

vii. **Running Royalties**. Licensee shall pay DFCI the following running royalties on Net Sales by Licensee, its Affiliates or its Sublicensees of each Royalty Bearing Product in a country in the Territory during the Royalty Term for such Royalty Bearing Product in such country as follows:

[***]

Notwithstanding anything to the contrary in this Agreement, a Royalty Bearing Product that has commenced its Royalty Term in a country shall be deemed a "Royalty Bearing Product" in such country until [***].

If (A) Licensee or any of its Affiliates consider it necessary, on advice of counsel, to obtain a license from any Third Party in order to avoid infringing such Third Party's intellectual property in the course of the development, manufacture or commercialization of a Royalty Bearing Product (any such license, a "Third Party License"), and (B) the Third Party License requires Licensee or its Affiliates to pay to such Third Party a royalty calculated as a percentage of Licensee's or its Affiliates' or any of their Sublicensees' sales or profits ("Third Party Royalties"), then in such case (A) and (B), Licensee may deduct [***] of the amount of Third Party Royalties actually paid by Licensee or its Affiliates to such Third Party(ies) with respect to any Royalty Bearing Product from running royalties payable to DFCI under this Agreement with respect to such Royalty Bearing Product; provided that, in no event shall payments to DFCI be reduced pursuant to this paragraph by more than [***] of the payments that would otherwise be payable pursuant to Section 3.1(g) for such Royalty Bearing Product.

viii. **Sublicense Income.** Licensee shall pay DFCI Sublicense Income during the Term as follows. Licensee shall pay Sublicense Income within [***] days of [***].

[***]

[***]

[***]

b. **Consequences of a Patent Challenge**. In the event that: (i) Licensee or any of its Affiliates brings a Patent Challenge (except as required under a court order or subpoena), or (ii) Licensee or any of its Affiliates assists another party in bringing a Patent Challenge (except as required under a court order or subpoena or (iii) a Sublicensee or any of its Affiliates brings a Patent Challenge or assists another in bringing a Patent Challenge and Licensee does not terminate such Sublicensee's Sublicense within [***] days after notice to Licensee of the relevant Patent Challenge from DFCI and (iv) DFCI does not choose to exercise its rights to terminate this Agreement pursuant to Section 8.2(h), then the royalties due under Section 3.1(g) shall be [***] of this Agreement. In the event that such a Patent Challenge is successful, Licensee will have [***]. In the event that a Patent Challenge is unsuccessful, Licensee shall reimburse DFCI for [***]. For the sake of clarity, royalties due during the pendency of the Patent Challenge shall be paid directly to DFCI and not placed in escrow or other account.

c. **Waiver or Deferral.** Waiver or deferral by DFCI of any payment owed under any paragraph under Section 3.1 may not be construed as a waiver or deferral of any subsequent payment owed by Licensee to DFCI.

4. – ROYALTY REPORTS, PAYMENTS AND FINANCIAL RECORDS

a. **Royalty Reports**. Within [***] days after [***], Licensee shall deliver to DFCI full, true and accurate reports of its activities and those of its Affiliates or Sublicensee(s), if any, relating to this Agreement or the rights licensed hereunder during the preceding [***]. These reports must include at least the following, each on a country-by-country and Royalty Bearing Product-by-Royalty Bearing Product basis:

i. [***];

ii. [***];

iii. [***];

iv. [***]; and

v. [***].

If multiple Royalty Bearing Products are covered by the license granted under this Agreement, Licensee shall [***]. Following receipt of such report, DFCI shall invoice Licensee for the royalties, if any, due and payable to DFCI under Section 3.1(g) and Licensee shall submit payment for amounts due under such invoice within [***] days of invoice receipt. All royalty reports provided to DFCI shall be deemed Confidential Information of Licensee.

b. **Record Keeping.**

i. **Books and Records.** Licensee shall keep, and shall require its Affiliates and Sublicensees to keep, true books of account containing an accurate record (together with supporting documentation) of all data necessary for determining the amounts payable to DFCI for a period of no less than [***] years following the end of the Calendar Year to which they pertain. Licensee shall keep its records at its

principal place of business or the principal place of business of the appropriate division of Licensee to which this Agreement relates and shall require its Affiliates and Sublicenses to keep their books and records in the same manner.

ii. **Inspections.** In order for DFCI to determine the correctness of any report or payment made under this Agreement, Licensee shall make its records available to DFCI for inspection for a period of [***] years following the end of the Calendar Year to which they pertain. Licensee shall also require any Affiliates or Sublicensees to make their records available for inspection by DFCI, in the same manner as provided in this Section 4.2(b). Upon [***] written notice to Licensee, DFCI may inspect the records during regular business hours by a certified public accountant selected by DFCI and reasonably acceptable to the licensed entity whose records are being inspected. In conducting inspections under this Section 4.2(b), Licensee agrees that DFCI's accountant may have access to [***]. DFCI shall inspect or audit Licensee's records no more than [***] and such inspection or audit shall be limited to records no more than [***]. All records and information contained therein shall be treated as Confidential Information of Licensee. [***].

c. Form of Payments and Taxes.

i. Licensee shall direct all payments to Dana Farber Cancer Institute in Boston, Massachusetts, or at such other place or in such other way as DFCI may reasonably designate. Payments shall either:

be paid by check payable to Dana-Farber Cancer Institute and sent to:

[***]
450 Brookline Ave.
BP335 Boston, MA 02215

or be paid by wire transfer, using the following information:

[***]

or be paid by wire transfers using ACH/EFT:

[***]

ii. Unless otherwise required under Applicable Law, Licensee shall pay all amounts payable to DFCI under this Agreement in United States Dollars without deduction or withholding for or on account of any taxes, exchange, collection or other charges that may be imposed by any country or political subdivision ("Taxes"). If any Taxes are required by Applicable Law to be withheld on amounts payable to DFCI under this Agreement, Licensee will pay to DFCI an additional amount as is necessary to ensure that the amount actually received by DFCI is equal to the amount of payment that would have been made if no such Taxes had applied. If Taxes are imposed on a payment to DFCI under Applicable Law, Licensee will, to the extent such is available, promptly provide evidence that Licensee has paid such Taxes to the proper taxing authority.

d. Currency Conversion. If any currency conversion is required in connection with any payment owed to DFCI, the conversion will be made at the buying rate for the transfer of such other currency as quoted by the Wall Street Journal on the last business day of the applicable accounting period in the case of any payment payable with respect to a specified accounting period or, in the case of any other payment, the last business day before the date the payment is due.

e. Interest. Any payment owed to DFCI under this Agreement that is not made when due will accrue interest beginning on the [***] day following the due date specified in ARTICLE III and such interest payment will be due immediately but in no event later than the payment of the overdue amount to DFCI. The interest will be calculated at the annual rate of the sum of (a) [***] percent ([***]%) plus

(b), the prime interest rate quoted by Bank of America on the date the payment is due, the interest being compounded on the last day of each Calendar Quarter; provided that the annual rate may not exceed the maximum legal interest rate permitted by Applicable Law. The payment of interest as required by this Section 4.5 does not foreclose or in any way limit DFCI from exercising any other rights or remedies it has as a consequence of the lateness of any payment.

5. – OPERATIONS UNDER THE LICENSE

a. Due Diligence.

i. **General Obligations**. Licensee shall use [***] efforts to bring one or more Royalty Bearing Products to the marketplace as soon as reasonably practicable, through a program of development, production and distribution. Such efforts [***]. After commercialization, Licensee shall continue [***] efforts to keep Royalty Bearing Products available to the public. Without limiting the foregoing or any provision of this Agreement, Licensee shall develop Royalty Bearing Products in accordance with the Development Plan.

ii. **Development Plan.** A development plan setting forth Licensee's plan for bringing the subject matter of the Patent Rights to practical application in Field of Use 2 is attached hereto as Schedule 2 (as amended from time to time pursuant to this Agreement, the "Development Plan"). The Development Plan must (i) be consistent with Licensee's general diligence obligations set forth in Section 5.1(a), (ii) set forth the particular Royalty Bearing Products and practical applications of Royalty Bearing Products that Licensee intends to develop in Field of Use 2, (iii) cite Licensee's specific goals and objectives for developing or commercializing the Patent Rights, and (iv) outline Licensee's plan for achieving the specific diligence obligations set forth in Section 5.1(c) below. The outline must include actual or projected financial resources or strategic alliances that will be required to meet such objectives.

iii. **Specific Diligence Benchmarks.** In addition to its obligations in Section 5.1(a), Licensee shall use [***] efforts to meet the specific effort and achievement benchmarks listed in Schedule 2 of this Agreement ("Diligence Benchmarks") in accordance with the timelines specified in Schedule 2. For purposes of this Section 5.1(c), DFCI will consider efforts of an Affiliate or Sublicensee under a Sublicense as efforts of Licensee.

iv. **Adjustments.** The Diligence Benchmarks and timelines set forth may be adjusted by mutual agreement by the Parties. If at any time Licensee determines that it is unlikely to meet one or more of the Diligence Benchmarks, it may so notify DFCI in writing as far in advance as practicable of the likely inability to achieve the applicable Diligence Benchmark and explain the technical, regulatory or other reasons therefore. At that time, Licensee and DFCI will work in good faith to determine a [***] adjustment of the Diligence Benchmark(s) and/or timelines specified for the Diligence Benchmarks. DFCI may accept or reject Licensee's proposed adjustment(s). If, despite their good faith negotiation, the Parties have not reached an agreement on an adjustment within [***] days following the date specified in Section 5.1(c) and Licensee has not otherwise met the Diligence Benchmark, then DFCI may terminate the exclusive license granted to Licensee for Field of Use 2 under Section 2.1(a) of this Agreement.

v. [***] **Reports.** On or before the [***] day [***], Licensee shall provide to DFCI a written report [***].

vi. **Failure to Perform.** Licensee's failure to satisfy any diligence obligations set forth in Section 5.1(a) through (c) and Section 5.1(e) may give rise to DFCI's ability to terminate the exclusive license granted to Licensee for Field of Use 2 under Section 2.1(a) of this Agreement in accordance with the terms of Section 8.3.

vii. **Decision Not to Further Exploit.** If at any time during the Term, Licensee decides not to exploit [***], either by itself, with an Affiliate or through sublicensing, Licensee shall promptly inform DFCI in writing. Unless within [***] days of such notice to DFCI, Licensee establishes to DFCI's satisfaction that [***], DFCI has the right to terminate the exclusive license under Section 2.1(a) of this Agreement insofar as it applies to [***] by providing written notice to Licensee. For clarity, any decision by Licensee to not develop or to not commercialize [***] shall be a decision not to "exploit" such [***] under this Section. In no event shall this Section limit or eliminate, in any way, DFCI's other rights and remedies under this Agreement and under Applicable Law, including DFCI's right to terminate this Agreement as described in Section 8.2.

b. **U.S. Manufacture.** Licensee shall manufacture Royalty Bearing Products leased, used or sold in the United States substantially in the United States to the extent required by 35 U.S.C. 204 and 37 C.F.R. 401 et. seq., as amended. Licensee shall also require any Affiliate(s) or Sublicensee(s) to comply with this U.S. manufacture requirement.

c. **Other Government Laws**. Licensee shall comply with, and ensure that its Affiliates and Sublicensees comply with, all Applicable Laws that relate to Royalty Bearing Products. These include but are not limited to FDA statutes and regulations, the Export Administration Act of 1979, as amended, codified in 50 App. U.S.C. 2041 et seq. and the regulations promulgated thereunder or other applicable export statutes or regulations.

d. **Patent Marking**. To the extent required by law, or if the failure to mark would reduce the rights of DFCI or Licensee to enforce the Patent Rights against infringers, Licensee shall, and shall require its Sublicensees and Affiliates to, use [***] efforts to mark, all Royalty Bearing Products sold in the United States with the word "Patent" and the number or numbers of Patent Rights applicable to the Royalty Bearing Product.

e. **Publicity; Use of Name.** Neither Party is permitted to use the name of the other Party, the Inventors, its related entities or its employees, or any adaptations thereof, in any advertising, promotional or sales literature, or in any securities report required by the Securities and Exchange Commission (except as required by law), without the prior written consent of the other Party in each case. However, Licensee may (a) refer to publications in the scientific literature by employees of DFCI or (b) state that a license from DFCI has been granted as provided in this Agreement.

f. **Confidentiality.** Information that is provided by a Party ("Disclosing Party") to the other Party ("Receiving Party") in connection with patent preparation, filing, prosecution and maintenance under the terms of ARTICLE VI (including that information, such as information regarding analyses or opinions of Third Party intellectual property) and any other proprietary or confidential information provided by a Disclosing Party to the Receiving Party under this Agreement is deemed to be Confidential Information of the Disclosing Party. The Receiving Party agrees that, during the Term, and for [***] years thereafter, to employ [***] efforts to maintain the Confidential Information secret confidential, such efforts to be [***]. The Confidential Information shall not be disclosed or revealed to anyone except employees or agents of or consultants of the Receiving Party who have a need to know the information and who have entered into a secrecy agreement under which such employees, agents, or consultants are required to maintain confidential the Confidential Information and such employees, agents, or consultants shall be advised by the Receiving Party of the confidential nature of the information and that the Confidential Information shall be treated accordingly. The Receiving Party's obligations under this Section shall not extend to any part of the information:

i. that can be demonstrated to have been in the public domain prior to the date of the disclosure;

ii. that can be demonstrated, from written records, to have been in the Receiving Party's possession prior to the disclosure;

iii. that becomes part of the public domain or publicly known by publication or otherwise, not due to any act or omission of the Receiving Party, its employees, agents or consultants; or

iv. that is demonstrated from written records to have been independently developed by or for the Receiving Party without reference to the Confidential Information.

Notwithstanding anything to the contrary in this Agreement, the Receiving Party may disclose the Disclosing Party's Confidential Information in order to comply with Applicable Law or a valid court order. Notwithstanding the foregoing, in the event the Receiving Party is required to make a disclosure of Confidential Information pursuant to the preceding sentence, it will, (x) to the extent permissible under Applicable Law, give [***] advance notice to the Disclosing Party of such disclosure to provide an opportunity for the Disclosing Party to challenge or limit the disclosure obligations, (y) use [***] efforts to secure confidential treatment of such Confidential Information and (z) use [***] efforts to avoid disclosure of Confidential Information.

g. **Terms of the Agreement**. Each Party agrees not to, and to cause its Affiliates not to, disclose to any Third Party the terms of this Agreement without the prior written consent of the other Party hereto, which consent shall not be withheld unreasonably, except each Party and its Affiliates may disclose the terms of this Agreement without such consent: (a) to advisors (including financial advisors, legal advisors and accountants), actual or potential acquisition partners or private investors, licensees and other financial parties on a reasonable need to know basis, in each case under appropriate confidentiality provisions substantially equivalent to those in this Agreement; or (b) to the extent necessary to comply with Applicable Law and court orders (including securities laws or regulations and the applicable rules of any public stock exchange); provided that in the case of clause (b), the disclosing Party or its Affiliate shall promptly notify the other Party and (other than in the case where such disclosure is necessary, in the reasonable opinion of the disclosing Party's legal counsel, to comply with securities laws or regulations) allow the other Party a reasonable opportunity to intervene to protect the confidentiality of the information and oppose such disclosure and, to the extent allowable by law, to seek limitations on the portion of the Agreement that is required to be disclosed. Where such disclosure is necessary, in the reasonable opinion of the disclosing Party's legal counsel, to comply with securities laws or regulations, the disclosing Party shall allow the other Party a [***] opportunity to review such proposed disclosure and suggest portions of such disclosure for confidential treatment, which suggestions the disclosing Party shall reasonably consider. Notwithstanding any other provisions of this Agreement: (x) the Parties may provide information about this Agreement and amounts paid as part of routinely prepared summary documents that do not disclose any terms that were not disclosed in a mutually agreed press release; (y) the Parties may make factual statements regarding the existence, nature, and type of this Agreement, provided that such statements do not disclose specific terms hereof; and (z) DFCI may report consideration to institutions, inventors or others to whom royalties are payable based on activities performed hereunder and to the government as necessary or required.

h. **Publications.**

i. If Licensee wishes to publish manuscripts, abstracts or the like describing the Patent Rights and inventions contained therein and containing any Confidential Information of DFCI, Licensee agrees to submit all such intended manuscripts, abstracts or the like to DFCI at least [***] days prior to any submission or other public disclosure and, at DFCI's request, to delete any Confidential Information of DFCI. If DFCI determines that the publication or intended presentation contains patentable subject matter that should be protected by the filing of a patent application before publication or disclosure, it may notify Licensee and, in such case, Licensee will grant an additional [***] day review period to permit the preparation and filing of a patent application.

ii. Notwithstanding anything to the contrary in this Agreement, DFCI retains the right to publish, present and otherwise publicly disseminate any results or other information stemming from the rights retained as set forth in Section 2.4, provided that such proposed publication or dissemination

may not contain Confidential Information of Licensee or its Affiliates or Sublicensees without Licensee's prior written consent for publication of such Confidential Information. DFCI agrees to submit all such intended publications or public disseminations to Licensee at least [***] days prior to any submission or other public disclosure and, at Licensee's request, to delete any Confidential Information of Licensee.

6. – PATENT PREPARATION, FILING, PROSECUTION AND MAINTENANCE

a. **Responsibility.** Subject to Section 3.1(b), DFCI, in its sole discretion, is responsible for preparing, filing, prosecuting and maintaining the patent applications and patents included within Patent Rights. For purposes of this Agreement, patent "prosecution" and "prosecuting" includes ex parte prosecution, interference proceedings, reissues, reexaminations, oppositions and all proceedings before a patent office in the Territory, including inter parties review, appeals and post grant review proceedings, and any judicial or other appeals of the foregoing. DFCI agrees to continue to prepare, file, prosecute and maintain the patent applications and patents included within Patent Rights for so long as (a) Licensee continues to meet its obligation to reimburse expenses [***]. As long as the license in Section 2.1(a) remains exclusive to Field of Use 2 subject to the non-exclusive license granted identified in Section 2.1(a), DFCI shall provide, or cause its agent to provide, to Licensee copies of relevant material correspondence between DFCI and the United States Patent Office or the various foreign patent offices with respect to the filing, prosecution and maintenance of Patent Rights and, to the extent practicable, give Licensee [***] opportunity to review and comment on such matters. DFCI shall consider Licensee's [***] comments in good faith.

Notwithstanding the foregoing, DFCI will (i) use [***] efforts to establish Patent Rights covering Field of Use 2, and will cooperate exclusively with Licensee to file, prosecute, and maintain in countries requested by Licensee, Patent Rights covering Field of Use 2, and (ii) not take any actions with respect to the filing, prosecution or maintenance of the Patent Rights that may adversely affect Licensee's rights under Patent Rights in Field of Use 2 or otherwise frustrate Licensee's ability to exclusively develop, manufacture and commercialize Royalty Bearing Products under Patent Rights in Field of Use 2.

b. Licensee designates the following individual or department for receiving the patent-related correspondence**:**

Fate Therapeutics, Inc.
ATTN: General Counsel
3535 General Atomics Court, Suite 200
San Diego, CA. 92121

Via email: [***]

c. **Cooperation.** Licensee shall cooperate with DFCI in preparing, filing, prosecuting and maintaining the patent applications and patents within the Patent Rights. Licensee shall provide prompt notice to DFCI of any matter that comes to its attention that may affect the patentability, validity or enforceability of any patent application or patent within the Patent Rights.

d. **Common Interest**. The Parties acknowledge and agree that, with regard to the preparation, filing, prosecution and maintenance of the Patent Rights, the interests of the Parties as licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. All non-public information disclosed by DFCI or DFCI's outside patent counsel to Licensee regarding preparation, filing, prosecution or maintenance of the Patent Rights, will be deemed Confidential Information. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Patent Rights or Confidential Information, including privilege under the common interest doctrine and similar or related doctrines.

e. **Patent Term Extension**. DFCI shall have the [***] to make decisions regarding, and to apply for and obtain, in each case in consultation with Licensee, patent term restoration for Patent Rights with respect to any Royalty Bearing Product in any country in the Territory under any statute or regulation equivalent or similar to 35 U.S.C. § 156, and DFCI will determine [***] which such Patent Rights will be extended (including, without limitation, by filing supplementary protection certificates and any other extensions that are now or in the future become available) as applicable to a Royalty Bearing Product.

f. **Unitary Patent System**. DFCI shall have the exclusive right to opt-in or opt-out of the EU Unitary Patent System for all Patent Rights. Without limiting the generality of the foregoing, Licensee shall not initiate any action with respect to a Patent Right that would result in DFCI being obligated to opt-in or opt-out under the EU Unitary Patent System with respect to such Patent Right prior to DFCI making a final, binding determination as to so opt-in or opt-out.

g. **Relinquishing Rights.** Licensee may surrender its licenses under any of the patents or patent applications within Patent Rights in any country of the Territory by giving [***] days advance written notice to DFCI. However, if Licensee is surrendering any patent or application within Patent Rights on which an inter parties review, post grant review proceeding, interference proceeding, other opposition or any appeal thereof has been declared or filed, the notice period is [***] days. If Licensee so surrenders its rights, it will remain responsible for all patent-related expenses incurred by DFCI before or during the applicable notice period. Thereafter, Licensee will have no further obligation to pay any patent expenses for the patents or patent applications that it surrendered. Notwithstanding the foregoing, if such surrender results in termination of all rights under this Agreement, then such surrender shall be deemed a termination of this Agreement in its entirety and the termination notice provision in Section 8.3 shall apply.

7. - PATENT INFRINGEMENT AND ENFORCEMENT

a. **Notice.** If, at any time during the term of this Agreement, Licensee becomes aware of any infringement of the Patent Rights in a particular country, it will promptly notify DFCI.

b. **Action by DFCI**.

i. **Procedure.** Subject to the terms of this ARTICLE VII, DFCI may, [***], (i) enforce the Patent Rights and prosecute apparent Third Party infringers when, in its judgment, such action may be reasonably necessary and justified and (ii) join Licensee as a party-plaintiff to any proceeding to pursue enforcement of any Patent Right(s) if required by Applicable Law.

ii. **Competitive Infringement.** Licensee may request DFCI to take steps to protect the Patent Rights from an apparent infringement by supplying DFCI (i) an opinion of qualified legal counsel demonstrating to DFCI's reasonable satisfaction good faith reason to believe that an infringement of one or more Patent Rights exists in a particular country in the Territory and (ii) with written evidence demonstrating to DFCI's reasonable satisfaction that the relevant Third Party infringer is developing, manufacturing or commercializing a product that is competitive to a Royalty Bearing Product being developed, manufactured, or commercialized by Licensee [***] (such infringement evidenced as set forth in clause (i) and (ii), a "Competitive Infringement"). DFCI shall have [***] months from the date of receiving satisfactory written evidence from Licensee of a Competitive Infringement to decide whether it will seek to terminate the Competitive Infringement. If DFCI notifies Licensee that it intends to prosecute the alleged infringer, then DFCI has [***] months from the date of its notice to Licensee to either (a) cause the Competitive Infringement to terminate or (b) initiate legal proceedings against the infringer before Licensee has the right to pursue enforcement under and subject to Section 7.3. If any such suit with respect to a Competitive Infringement is brought at Licensee's request by DFCI in its own name, or jointly with Licensee if required by Applicable Law, it will be [***] on DFCI's own behalf, but DFCI shall not be obligated [***].

iii. **Licensee's Right to Join.** Licensee independently has the right to join any legal proceeding brought by DFCI under this Section 7.2 [***]. If Licensee elects to join as a party plaintiff pursuant to this Section 7.2(c), Licensee may jointly participate in the action with DFCI with counsel of its own choosing, but DFCI's counsel will be lead counsel and DFCI shall have final decision-making authority with respect to such action.

c. Action by Licensee.

i. **Procedure.** If DFCI notifies Licensee within the [***] period set forth in Section 7.2(b) that it does not intend to prosecute the Competitive Infringement or if DFCI fails to cause the Competitive Infringement to terminate or bring legal proceeding to compel termination within [***] months of the date of its notice to Licensee that it intends to prosecute the alleged infringer, then Licensee may initiate legal proceedings to pursue enforcement of the relevant Patent Right(s) [***] against the alleged infringer, [***]; provided however that if DFCI notifies Licensee that its election not to pursue enforcement of the alleged infringement is because such enforcement may, in the reasonable opinion of its legal counsel, adversely affect the interests of DFCI under the Patent Rights, Licensee shall have no right to pursue such enforcement under this Agreement and provided further that any legal proceedings brought by Licensee must include enforcement of any patent or patent application owned by Licensee or its Affiliate that Licensee has good faith reason to believe is also infringed by the relevant alleged infringer's actions related to the Competitive Infringement. Before Licensee commences any legal proceeding with respect to the Competitive Infringement, Licensee shall consider in good faith the views of DFCI, particularly as they relate to the potential effects on the public interest. Licensee has the right to join DFCI as a party-plaintiff if required by Applicable Law, [***]. Licensee shall keep DFCI updated as to any and all material developments in the prosecution of a Competitive Infringement and DFCI shall have a right to comment on the strategy and key submissions related to the prosecution with any [***] comments of DFCI to be implemented and included by Licensee in good faith. If Licensee exercises its right to pursue prosecution of a Competitive Infringement, Licensee shall be obligated to defend any cross claim or counterclaim or action for declaratory judgment related to the Patent Rights or Royalty Bearing Product; provided, however, that DFCI shall have the right to intervene and assume sole control of such defense [***]. Licensee acknowledges that its second right to enforce under this Section 7.3(a) may be non-exclusive with respect to another licensee or other licensees of DFCI.

ii. **DFCI's Right To Join.** DFCI independently has the right to join any legal proceeding brought by Licensee under this Section 7.3(b) [***]. If DFCI elects to join as a party plaintiff pursuant to Section 7.8, DFCI may jointly participate in the action with Licensee, but Licensee's counsel will be lead counsel and Licensee shall have final decision-making authority with respect to such action.

iii. **DFCI's Right to Enforce.** If Licensee (i) informs DFCI that it does not intend to prosecute a Competitive Infringement pursuant to its rights under Section 7.3(a), (ii) fails to cause the Competitive Infringement to terminate or bring legal proceedings to compel termination within [***] months of DFCI's notice or failure giving rise to Licensee's right to enforce in Section 7.3(a) or (iii) does not use, in DFCI's reasonable good faith opinion, [***] efforts to prosecute a Competitive Infringement, DFCI may initiate legal proceedings to pursue enforcement of the relevant Patent Right(s) against the alleged infringer, [***].

d. Settlement. Regardless of whether DFCI is joined or joins any legal proceeding initiated by Licensee**,** no settlement, consent judgment or other voluntary final disposition of a legal proceeding commenced under this ARTICLE VII may be entered into without the prior written consent of DFCI. In addition, Licensee shall not settle or resolve, whether formally or informally, a contractual dispute with any Third Party, including a Sublicensee, in a manner that admits, or provides support for, the invalidity or unenforceability of the Patent Rights or would diminish, impair or eliminate DFCI's rights under a Sublicense with respect to the Patent Rights without DFCI's prior written consent, such consent not to be unreasonably withheld if DFCI has had an opportunity to comment on the settlement and Licensee has incorporated DFCI's [***] comments in good faith.

e. **Cooperation.** If one Party initiates legal proceedings to enforce the Patent Rights pursuant to this ARTICLE VII, the other Party shall cooperate with and supply all assistance reasonably requested by the Party initiating the proceedings, at the initiating Party's request [***] unless otherwise expressly set forth herein. Neither DFCI nor Licensee will notify an alleged infringer of alleged infringement or put such infringer on notice of the existence of any of the Patent Rights, without first obtaining the written permission of the other Party, which permission shall not be unreasonably withheld.

f. **Reimbursement.** Except as otherwise set forth herein, the Party responsible for the costs of any action under this ARTICLE VII shall reimburse [***] within [***] days of [***].

g. **Distribution of Amounts Paid by Third Parties.**

i. In any legal proceeding brought by DFCI under Section 7.2 or by Licensee under Section 7.3, any damages or other amounts recovered as a result of the proceeding will be distributed as follows:

1. [***]

2. [***]

ii. If DFCI initiates a legal proceeding under Section 7.3(c), [***].

h. **Declaratory Judgment Actions.**

i. In the event that any Third Party (i) initiates a declaratory judgment action in a federal court alleging the invalidity or unenforceability of any of the Patent Rights or (ii) brings an infringement action against Licensee or its Affiliates or Sublicensees because of Licensee's exercise of the rights granted Licensee under this Agreement (with the exception of a counterclaim by a Third Party following an enforcement action by DFCI pursuant to Section 7.2 or Section 7.3(c)), then Licensee shall, subject to Section 7.4, have the right to defend such action under its own control [***]; provided, however, that DFCI shall have the right to intervene and assume sole control with respect to the Patent Rights (but not any patent or patent application owned by Licensee or its Affiliate) of a declaratory judgment action alleging the invalidity or unenforceability of any of the Patent Rights, [***].

ii. [***]; provided, however, that any recovery for infringement of the Patent Rights by a Third Party will be distributed as described in Section 7.7.

i. **Paragraph IV Type Notices.** Without limiting any other obligation under this Agreement, each Party will immediately (but in no event more than [***] days [***]) give written notice to the other of any certification of which it becomes aware filed pursuant to any statutory or regulatory requirement in any country in the Territory similar to 21 U.S.C. § 355(b)(2)(A)(iv) or § 355(j)(2)(A)(vii)(IV) (or any amendment or successor statute thereto) claiming that any Patent Right Covering any Royalty Bearing Product is invalid or that infringement will not arise from the development, manufacture, use or commercialization in the Territory of such Royalty Bearing Product by a Third Party. Licensee shall promptly provide to DFCI copies of all correspondence by or to Licensee or its Affiliates related to such certification. For clarity, the receipt of a certification as described in this Section 7.9 shall be deemed to be an act of infringement subject to action under Section 7.2 or 7.3, as applicable.

8. – TERM AND TERMINATION

a. **Term.** The term of this Agreement shall commence on the Effective Date and remain in effect until, unless terminated earlier under the provisions of this Agreement, the expiration date of the last to expire of patents within Patent Rights (such time period, the "Term").

b. **Termination of Agreement by DFCI.** DFCI has the right to immediately terminate this Agreement and all licenses granted hereunder by providing Licensee with written notice of termination, upon the occurrence of any of the following events:

i. Licensee fails to pay any royalty or other payment pursuant to this Agreement that has become due and is payable under ARTICLE III or ARTICLE IV of this Agreement and has not cured the default by making the required payment, together with interest due, within [***] days of receiving a written notice of default from DFCI requesting such payment.

ii. Licensee defaults in its obligations to procure and maintain insurance under Section 9.2.

iii. An officer of the Licensee, its Affiliate or Sublicensee is convicted of a felony relating to the manufacture, use, sale or importation of one or more Royalty Bearing Products.

iv. Licensee has granted a Sublicense on terms inconsistent with the material terms required of Sublicenses hereunder and Licensee has not cured the default by satisfying such obligation within [***] days of receiving written notice of default from DFCI.

v. Licensee materially breaches any other provision of this Agreement, unless Licensee has cured the breach within [***] days of receiving written notice from DFCI specifying the nature of the breach.

vi. Licensee becomes insolvent, makes an assignment for the benefit of creditors, or has a petition in bankruptcy filed for or against it.

vii. Licensee or any of its Affiliates, Sublicensees or Sublicensees' Affiliates directly or indirectly brings a Patent Challenge or assists others in bringing a Patent Challenge, in each case except as may be required under a court order or subpoena.

c. **Termination of exclusive license**. DFCI may terminate the exclusive license granted to Licensee for Field of Use 2 under Section 2.1(a) of this Agreement if Licensee fails to comply materially with any of the diligence obligations provided for in [***], and Licensee has not cured the default by satisfying such obligation within [***] days of receiving written notice of default from DFCI.

d. **Termination by Licensee.**

Licensee has the right to terminate this Agreement without cause in its entirety or on a Royalty Bearing Product-by-Royalty Bearing Product basis or country-by-country basis by giving DFCI [***] days prior written notice and paying all amounts due to DFCI through such effective date of termination. Upon such termination, Licensee shall cease all use and sales of Licensed Products and Licensed Processes which would be infringed by Valid Claims in those particular country(ies) applicable to such termination, subject to Section 8.5(d).

e. **Effect of Termination**.

i. **No Release.** Upon termination or expiration of this Agreement for any reason, nothing in this Agreement may be construed to release either Party from any obligation that accrued prior to, or that are expressly indicated to survive, the effective date of the termination or expiration, as applicable.

ii. **Survival.** The provisions of ARTICLE I (to the extent defined terms are contained in the following Articles and Sections), Section 3.1(a) (Past Patent Expenses), ARTICLE IV (Royalty Reports, Payments and Financial Records), Section 5.3 (Other Government Laws), Section 5.5 (Publicity – Use of Names), Section 5.6 (Confidentiality), Section 5.7 (Terms of the Agreement), Section 6.4 (Common Interest), Section 7.7 (Distribution of Amounts Paid by Third Parties), Section 8.4 (Effect of Termination), ARTICLE IX (Indemnification, Defense and Insurance), Section 10.3 (Warranty

Disclaimers; Limitation of Liability), ARTICLE XI (Notices), ARTICLE XII (Dispute Resolution) and all of ARTICLE XIII (Miscellaneous) except Section 13.3 (Assignment) and, solely with respect to Royalty Bearing Products that Licensee has the right to exploit in any way following termination of this Agreement pursuant to Section 8.5(c)(iii) or Section 8.5(d), Section 3.1(e) (Milestone Payments), Section 3.1(g) (Running Royalties), Section 5.2 (U.S. Manufacture) and Section 5.4 (Patent Marking), survive termination or expiration of this Agreement.

iii. **Rights**.

1. Upon termination of this Agreement for any reason all rights and licenses granted to Licensee under the terms of this Agreement will terminate, subject to Section 8.5(d).

2. Following the termination of this Agreement (but not upon expiration of this Agreement in accordance with the terms hereof), at DFCI's request, Licensee shall deliver to DFCI, and DFCI and its licensees shall be free to use for all purposes any unused Biological Materials provided by DFCI to Licensee under this Agreement and any progeny and unmodified derivatives thereof.

3. Without limiting any other provision of this Agreement, in the event that, following the effective date of termination of this Agreement, Licensee, its Affiliates or its Sublicensees sell or have sold any product that is a Royalty Bearing Product in a country in the Territory or any other product that, if the Agreement had not been terminated, would have been deemed a Royalty Bearing Product in such country under the terms of Section 3.1(g), Licensee's obligation to pay DFCI royalties and milestones with respect to such Royalty Bearing Products pursuant to Section 3.1 shall survive termination of this Agreement.

iv. **Inventory.** Licensee, any Affiliate(s) and any Sublicensees whose Sublicenses are not converted as provided in Section 8.5(f), may, after the effective date of termination, sell all Royalty Bearing Products that are in inventory or have otherwise been distributed with the intent to sell as of the date of written notice of termination, and complete and sell Royalty Bearing Products which the licensed entity(ies) can clearly demonstrate were in the process of manufacture as of the date of written notice of termination, provided that Licensee shall pay to DFCI the royalties thereon as required by ARTICLE III and shall submit the reports required by ARTICLE IV on the sales of Royalty Bearing Products.

v. **Return of Confidential Information.** Within [***] days of the effective date of any termination of this Agreement (but not the expiration of this Agreement in accordance with the terms hereof), Licensee shall, at DFCI's option, either return or destroy all materials relating to or containing Confidential Information of DFCI (including the Biological Materials), except to the extent such Confidential Information of DFCI is maintained by Licensee as part of a permitted disclosure under Section 5.6. Notwithstanding the foregoing, (i) Licensee will be permitted to retain one copy of such materials for archival and legal compliance purposes and (ii) Licensee will not be required to delete or destroy any electronic back-up tapes or other electronic back-up files that have been created solely by the automatic or routine archiving and back-up procedures of Licensee, to the extent created and retained in a manner consistent with its or their standard archiving and back-up procedures.

vi. **Sublicenses.** Any Sublicenses will terminate contemporaneously with this Agreement, provided however, that any Sublicensee not in default under its Sublicense may request conversion of the Sublicense to a license directly between DFCI and Sublicensee on or before the [***] day following termination of this Agreement. DFCI shall not unreasonably withhold its acceptance of such conversion, however, as a condition of DFCI's acceptance, the Sublicensee must first agree to be bound by all of the provisions of this Agreement.

9. – INDEMNIFICATION, DEFENSE AND INSURANCE

a. Indemnification and Defense.

i. Licensee shall indemnify, defend and hold harmless DFCI and its trustees, officers, medical and professional staff, employees, and agents and their respective successors, heirs and assigns (collectively, the "Indemnitees" and each, an "Indemnitee") against any liability, damage, loss or expense (including attorneys' fees and expenses of litigation) incurred by or imposed upon the Indemnitees, or any one of them, in connection with any claims, suits, actions, demands or judgments arising from or occurring as a result of: (i) the research, development, design, production, manufacture, sale, use in commerce, lease, promotion or other exploitation of any product, process or service relating to, or developed pursuant to, this Agreement (including any Royalty Bearing Product) by Licensee or by a Sublicensee, Affiliate or agent of Licensee, (ii) a breach of this Agreement by Licensee or (iii) any activities carried out pursuant to this Agreement or the exercise of any rights granted under this Agreement by Licensee, its Affiliates, Sublicensees or permitted subcontractors.

ii. If any such action is commenced or claim made or threatened against DFCI or other Indemnitees as to which Licensee is obligated to indemnify it (them) or hold it (them) harmless, DFCI or the other Indemnitees shall promptly notify Licensee of such event; provided that any failure to do so shall not affect the Indemnitee's right to indemnification hereunder, except to the extent that such failure or delay impairs the Licensee's ability to defend or contest any such claim. The right of Licensee to assume the defense of any action is limited to that part of the action commenced against DFCI and/or Indemnitees that relates to Licensee's obligation of indemnification and holding harmless Licensee shall assume the defense of any suit or claim for which indemnification is sought under this Section 9.1. Licensee shall, [***], provide attorneys reasonably acceptable to DFCI to defend against any actions brought or filed against any Indemnitee hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought. Licensee shall keep DFCI informed of the progress of the indemnified claim. DFCI may participate in the defense thereof [***]. Licensee may not enter into any settlement, consent judgment, or other voluntary final disposition of any claim that has an adverse effect on the rights of any Indemnitee(s) hereunder or admits any wrongdoing or fault by any Indemnitee(s) or imposes on any Indemnitee(s) any payment or other liability or obligation, without the prior written consent of DFCI.

iii. Licensee shall require any Affiliates or Sublicensee(s) to indemnify, hold harmless and defend DFCI under the same terms set forth in this ARTICLE IX.

b. Insurance.

i. At such time as any product, process or service relating to, or developed pursuant to, this Agreement is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Licensee or by a Sublicensee, Affiliate or agent of Licensee, Licensee shall, [***], procure and maintain policies of commercial general liability insurance in amounts not less than $[***] and naming the Indemnitees as additional insureds. Such commercial general liability insurance must provide (a) product liability coverage and (b) contractual liability coverage for Licensee's indemnification under Section 9.1 of this Agreement. If Licensee elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of $[***] annual aggregate), such self-insurance program must be acceptable to the DFCI and the DFCI's associated Risk Management Foundation. The minimum amounts of insurance coverage required under these provisions may not be construed to create a limit of Licensee's liability with respect to its indemnification obligation under Section 9.1 of this Agreement.

ii. Licensee shall provide DFCI with written evidence of such insurance upon request of DFCI. Licensee shall provide DFCI with written notice at least [***] days prior to the cancellation, non-renewal or material change in such insurance; provided, however, that Licensee shall not be

required to provide written notice in the event Licensee has procured replacement insurance that complies with the requirements of Section 9.2. In the event Licensee does not maintain insurance that complies with the requirements of Section 9.2 for a period of [***] consecutive days, DFCI shall have the right to terminate this Agreement effective at the end of such [***] day period without any notice or additional waiting periods.

iii. Licensee shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (i) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Licensee or by a Sublicensee, Affiliate or agent of Licensee and (ii) a [***] period after the period referred to in clause (i) of this Section 9.2(c) above which in no event shall be less than [***] years.

iv. Licensee shall require any Affiliates or Sublicensee(s) to maintain insurance in favor of DFCI and the Indemnitees under the same terms set forth in this Section 9.2.

10. – REPRESENTATIONS AND WARRANTIES; LIABILITY LIMITATIONS

a. **Representations, and Covenants of Licensee.** Each Party represents, and covenants to the best of its knowledge as of the Effective Date that (a) it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization; (b) it has the authority and right to enter into and perform its obligations under this Agreement, (c) as of the Effective Date, the execution, delivery and performance of this Agreement does not conflict with, or constitute a breach of, any order, judgment, agreement or instrument to which it is a Party or, to its knowledge, is otherwise bound, (d) no consent of any Third Party, including without limitation any governmental authority, is required for such Party to execute, deliver and perform under this Agreement, and (e) the Licensee will comply, and will ensure that its Affiliates and Sublicensees if applicable comply, with all Applicable Laws in the performance of its obligations and exercise of its rights under this Agreement.

b. DFCI hereby represents that as of the Effective Date (i) it is the sole and exclusive owner or appointed agent for licensing of all right, title and interest in and to the Patent Rights; (ii) it has the power and authority to grant the licenses provided for herein to Licensee, and (iii) that to the best of its knowledge, it has not earlier granted, or assumed any obligation to grant, with the exception of the Third Party non-exclusive license to Field of Use 1, any rights in such Patent Rights to any Third Party that have not been waived that would conflict with the rights granted to Licensee herein.

c. **Warranty Disclaimers; Limitation of Liability.**

i. DFCI MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY ROYALTY BEARING PRODUCT, PATENT RIGHT, TRADEMARK, SOFTWARE, NON-PUBLIC OR OTHER INFORMATION, OR TANGIBLE RESEARCH PROPERTY, LICENSED OR OTHERWISE PROVIDED TO LICENSEE HEREUNDER AND HEREBY DISCLAIMS THE SAME.

ii. DFCI DOES NOT WARRANT THE VALIDITY OF THE PATENT RIGHTS LICENSED HEREUNDER AND MAKES NO REPRESENTATION WHATSOEVER WITH REGARD TO THE SCOPE OF THE PATENT RIGHTS OR THAT SUCH PATENT RIGHTS MAY BE EXPLOITED BY LICENSEE, AFFILIATE OR SUBLICENSEE WITHOUT INFRINGING OTHER PATENTS.

iii. THE LIABILITY OF DFCI, ITS AGENTS, OR ITS EMPLOYEES, WITH RESPECT TO ANY AND ALL SUITS, ACTIONS, LEGAL PROCEEDINGS, CLAIMS, DEMANDS, DAMAGES, COSTS AND EXPENSE ARISING OUT OF THE PERFORMANCE OR NON PERFORMANCE

OF ANY OBLIGATION UNDER THIS AGREEMENT WHETHER BASED ON CONTRACT, WARRANTY, TORT (INCLUDING WITHOUT LIMITATION NEGLIGENCE), STRICT LIABILITY, STATUTORY OR OTHERWISE SHALL BE LIMITED TO DIRECT, ACTUAL DAMAGES INCURRED AS A RESULT OF DFCI'S FAILURE TO PERFORM ITS OBLIGATIONS AS REQUIRED BY THIS AGREEMENT AND EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, DFCI SHALL IN NO EVENT BE LIABLE FOR ANY LOST PROFITS, LOST BUSINESS OPPORTUNITY OR INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND.

11. – NOTICES

Unless otherwise expressly specified in this Agreement, reports, notices and other communications under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed given only if delivered by hand, recognized national overnight courier (with confirmation) or registered or certified mail with postage prepaid and return receipt requested, to the following addresses of the Parties:

If to DFCI: Senior Director, Licensing
Dana-Farber Cancer Institute, Inc.
450 Brookline Ave.
Boston, MA 02215

With a copy to: Chief Innovation Officer
Dana-Farber Cancer Institute, Inc.
450 Brookline Ave.
Boston, MA 02215

If to Licensee: Fate Therapeutics, Inc.
ATTN: Office of the Chief Executive Officer
3535 General Atomics Court, Suite 200
San Diego, CA. 92121

With a copy to: Fate Therapeutics, Inc.
ATTN: General Counsel
3535 General Atomics Court, Suite 200
San Diego, CA. 92121

Such notice shall be deemed to have been given and effective as of the date of receipt. A Party may change its contact information immediately upon written notice to the other Party in the manner provided in this ARTICLE XI.

12. – DISPUTE RESOLUTION

a. **Negotiation between the Parties.** Subject to Section 12.2, the Parties shall first attempt to resolve any controversy that arises from this Agreement, or claim for breach of the Agreement, by good faith negotiations, first between their respective business development representatives and then, if necessary, between senior representatives for the Parties, such as the Senior Vice-President for Research or President of DFCI and the General Counsel and/or President of Licensee.

b. **Injunctive Relief.** Notwithstanding anything to the contrary in this Agreement, each Party may seek a preliminary injunction or other provisional equitable relief if it believes that such action is necessary to avoid irreparable harm to such Party or preserve such Party's rights under this Agreement.

13. - MISCELLANEOUS

a. **Independent Contractors.** For the purpose of this Agreement and all services to be provided hereunder, both Parties are and will be deemed to be, independent contractors and not agents or employees of the other. Neither Party has authority to make any statements, representations or commitments of any kind, or to take any action, that will be binding on the other Party. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees for any purpose, including tax purposes, or to create any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party.

b. **Severability.** If any one or more of the provisions of this Agreement is held to be invalid, illegal or unenforceable, (a) the validity, legality or enforceability of the remaining provisions of this Agreement will not in any way be affected or impaired thereby and shall remain in full force and effect and (b) the Parties shall negotiate in good faith to modify the Agreement to preserve (to the extent possible) their original intent.

c. **Assignment.** DFCI may assign, delegate or subcontract any or all of its rights or obligations under this Agreement at any time without the prior consent of Licensee. Except as expressly permitted in this Agreement, Licensee may not assign, delegate or subcontract any of its rights or obligations under this Agreement, in part or in whole, without the express written consent of DFCI, which consent DFCI will not unreasonably withhold; provided that Licensee may assign this agreement to a successor in interest in conjunction with the sale of all or substantially all of its assets, so long as such successor shall agree in writing to be bound by the terms and conditions hereof prior to such assignment. Any attempted assignment not permitted under this Section 13.3 shall be null and void.

d. **Change of Control.** Licensee will notify DFCI in writing promptly (and in any event within [***] days) following the entering into of a definitive agreement with respect to a Change of Control.

e. **Entire Agreement**. This Agreement (including any schedules, exhibits or the like) contains the entire agreement between the Parties with respect to the subject matter. No verbal agreement, conversation or representation between any officers, agents, or employees of the Parties either before or after the execution of this Agreement may affect or modify any of the terms or obligations herein contained.

f. **Modifications in Writing.** No change, modification, extension, or waiver of this Agreement, or any of the provisions herein contained is valid unless made in writing and signed by a duly authorized representative of each Party.

g. **Governing Law.** The validity and interpretation of this Agreement and the legal relations of the Parties to it are governed by the laws of [***] without regard to any choice of law principle that would dictate the application of the law of another jurisdiction.

h. **Further Assurance.** Each Party shall duly execute and deliver or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

i. **Interpretation.** The captions are provided for convenience and are not to be used in construing this Agreement. Unless the context of this Agreement otherwise requires, (a) words of any gender include either or both genders; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the term “or” shall have the inclusive meaning of the term “and/or”; (d) “including” and its cognates shall have the non-limiting meaning of “including, without limitation”; (e) the term “will” shall have the same meaning and import as the term “shall”; (f) the terms “hereof,” “herein,” “hereby” and derivative or similar words refer to this entire Agreement; (g) the terms “Article” or “Section” refer to the specified Article or Section of this Agreement.

j. **Construction.** The Parties agree that they have participated equally in the formation of this Agreement and that the language herein should not be presumptively construed against either of them.

k. **Counterparts.** This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, and together shall constitute one and the same agreement and shall become effective when one (1) or more counterparts have been signed by each of the Parties and delivered to the other Party, it being understood that both Parties need not sign the same counterpart. This Agreement, following its execution, may be delivered via PDF copies or other form of electronic delivery, which shall constitute delivery of an execution original for all purposes.

Signature Page To Follow

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of Effective Date.

DANA-FARBER CANCER INSTITUTE, INC. (DFCI)

By: [***]

Name: [***]

Title: Senior Director, Licensing

Date: April 9, 2020

Fate Therapeutics, Inc. (Licensee)

By: /s/ Scott Wolchko

Name: Scott Wolchko

Title: President and CEO

Date: April 9, 2020

SCHEDULE 1

Patent Rights are limited only to the [***].

SCHEDULE 2

[***]

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statements (Form S-3 Nos. 333-213590, 333-215460, 333-219987, and 333-260772) of Fate Therapeutics, Inc., and
2. Registration Statements (Form S-8 Nos. 333-191576, 333-194625, 333-202690, 333-209392, 333-211484, 333-215880, 333-219989, 333-223521, 333-230152, 333-236835, and 333-253459) pertaining to the 2007 Equity Incentive Plan, the 2013 Stock Option and Incentive Plan, 2013 Employee Stock Purchase Plan, and the Inducement Equity Plan of Fate Therapeutics, Inc.;

of our reports dated February 28, 2022, with respect to the consolidated financial statements of Fate Therapeutics, Inc. and the effectiveness of internal control over financial reporting of Fate Therapeutics, Inc. included in this Annual Report (Form 10-K) of Fate Therapeutics, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

San Diego, California
February 28, 2022

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, J. Scott Wolchko, certify that:

1. I have reviewed this Annual Report on Form 10-K of Fate Therapeutics, Inc.;

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

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

4. The registrant's other certifying officer 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 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.

Date: February 28, 2022

/s/ J. Scott Wolchko
J. Scott Wolchko
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Edward J. Dulac III, certify that:

1. I have reviewed this Annual Report on Form 10-K of Fate Therapeutics, Inc.;

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

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

4. The registrant's other certifying officer 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 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.

Date: February 28, 2022

/s/ Edward J. Dulac III
Edward J. Dulac III
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, J. Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based upon my knowledge:

(1) this Annual Report on Form 10-K of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

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

Date: February 28, 2022

/s/ J. Scott Wolchko
J. Scott Wolchko
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Edward J. Dulac III, Chief Financial Officer of Fate Therapeutics, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based upon my knowledge:

(1) this Annual Report on Form 10-K of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

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

Date: February 28, 2022

/s/ EDWARD J. DULAC III
Edward J. Dulac III
Chief Financial Officer
(Principal Financial and Accounting Officer)